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Implementation of a training program to increase knowledge, improve attitudes and reduce nursing care omissions in patients with dementia: a mixed method study protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030459
Article Type:	Protocol
Date Submitted by the Author:	17-Mar-2019
Complete List of Authors:	Evripidou, Melina; Cyprus University of Technology, Nursing Merkouris, Anastasios; Cyprus University of Technology Faculty of Health Sciences, Nursing, School of Health Sciences Charalambous, Andreas; Cyprus University of Technology; Turun Yliopisto, Nursing Papastavrou, Evridiki; Cyprus University of Technology, nursing
Keywords:	Rationing < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL ETHICS, MEDICAL EDUCATION & TRAINING, Dementia < NEUROLOGY

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Implementation of a training program to increase knowledge, improve attitudes and reduce nursing care omissions in patients with dementia: a mixed method study protocol.

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Keywords: *nurses, dementia, knowledge, attitudes, care*

Word counts: 4525

ABSTRACT

Introduction: There is evidence showing that when nurses have to ration their time because of a lack of resources, older patients and especially those with dementia have a lower care priority. The purpose of this study is to investigate the level of knowledge and attitudes of nurses towards dementia care and apply a training program, resulting in the improvement of the quality of nursing care, through the reduction of care omissions. The program will be enriched by an observation study of the care of patients with dementia to identify areas of missed care. The development of the training program is in accordance with the WHO (2017), recommendations for training all healthcare professionals about dementia.

Method and analysis: This study will follow a mixed methodology consisting of three stages; 1) evaluation of the level of nurses' knowledge and attitudes towards dementia care through the use of structured questionnaires, 2) observational study to evaluate nursing care in clinical settings, in order to detect any missed care, 3) quasi-experimental study, through the implementation of the training program in order to increase nurses' knowledge, improve attitudes and consequently to promote care for patients with dementia. The data will be analyzed with descriptive and inferential statistics with the use of the SPSS 24.0 and with content analysis as regards the observation data.

Ethics and dissemination: The protocol was approved by the National Bioethics committee and other local committees (EEBK: 2018.01.02). The participants gave their informed consent and the anonymity and confidentiality, as well as the protection of data were respected. The results of the study will be disseminated in peer-reviewed

international journals and conferences. If the intervention is successful, the training package will be given to the Continuous education unit of the National Professional Association in order to be used at a regular basis.

Article summary

Strengths of the study

- The main strength of the study lies in the fact that missed care that is mainly measured through self-reporting instruments, will be detected through observation, increasing the innovation of the methodological approach of the problem.
- The educational intervention will focus not only to dementia knowledge deficits, but it will also address specific areas of missed care for patients with dementia.

Limitations of the study

- The intervention will last for only one day and it is not certain that the effects will last for a long time, meaning that there is a need to repeat educational interventions at a later stage.

INTRODUCTION

People with dementia (PwD) occupy 25% of hospital beds [1] and this number is expected to triple by 2050, considering the rapid epidemiological increment of the disease [2]. This group of patients is characterized by cognitive impairment placing them in an unfavorable position to demand the best possible care like other patients [3] and consequently they might be in great danger for neglect. The multidimensional problem of dementia and patients' complex needs remain unmet in correlation with the increase in life expectancy, inevitably leads to the need of investigating this topic. WHO 2017 [2], has highlighted the importance of the problem about dementia care in a global action plan on the public health response to dementia and set as a target 75% of countries to develop national policies, plans, policies either embedded with existing policies either independent until 2025 [2].

Studies have indicated that nurses have negative attitudes [4,5,6] and low level of knowledge towards dementia care[7,8,9,10], resulting in the assumption that those patients are in danger of care discounts. Nurses have a key role for improvement of quality of care as they are the ones who have most contact and time with the patients. The acquisition of a high level of knowledge and positive attitudes will upgrade nursing ethics especially compassion, cognitive and emotional empathy for PwD among nurses, resulting in the promotion of quality of care. A significant part of the WHO global plan is training health providers to the specials needs and management of care of people with dementia. This target in order to be succeeded [2], recommends the development of training programs for all heath professional and the encouragement to adopt positive attitudes. Raising understanding and training will help to reinforce health care and

improve social results, mainly quality of life of PwD and their carers, even the wider society leading to better living experience and settings for those people.

PwD are more vulnerable to care than older people, as due to their cognitive impairment they cannot react or demand better quality of care, so they are often marginalized and endangered from mistakes, omissions or even mistreatment, in relation with other groups of patients. This fact is attributed to the multidimensional nature, the memory and behavior problems, the comorbidities and the complexity of care as well as with the associated management problems. As a vulnerable group of people, PwD are in danger for abuse or neglect. According to the [11], the concept of "mistreatment" in the elderly is defined as "*the only or repetitive act, or the lack of appropriate action, arising in any relationship where there is the expectation of confidence harm or risk to the elderly person*". The concept of "vulnerability" is defined as the reduced ability of an individual or group to predict, cope, resist and recover from the effects of natural or man-made risks [12]. The concept is relative and dynamic in both directions. During 2009, non-deliberate injury was the 7th cause associated with mistreatment of 65+ people [13,14]. Several studies have shown that the older people are at greater risk of neglect and the problem is more complicated by taking into account the level of co-morbidity and potential risk [15,16,17,18]. A study [19], have shown that chronic cases and the elderly, who had no apparent and immediate effects from the treatment, were often marginalized by health professionals. This focus on medical objectivity and impartiality is clearly rational and legitimate, but the consequences may be undesirable.

Highlighting the ethical perspective of missed nursing care it seems that this phenomenon undermines the violation of fundamental human rights. People over the age of 65 with

1
2
3 cognitive decline are often overlooked of their lived experienced and the preservation of
4 human rights [3]. In fact, people with "silent minds" are deprived of their liberty by
5 denying civil and political rights to society or even during hospitalization. For PwD more
6 emphasis is given on providing basic care and supervision rather than integrating them
7 into the wider community, so the human rights of those individuals are marginalized [20].
8 In addition, the political controversy over the human rights of people with dementia
9 focuses on the right to respect and dignity [21], ignoring the fundamental rights of
10 freedom and decision-making [20].

11
12 In nursing the topic of missed care, although it has been proven to exist since 2009 [22],
13 is hardly acknowledged or discussed. The problem has recently brought up in the nursing
14 scientific agenda through a European project
15 (http://www.cost.eu/COST_Actions/ca/CA15208) that aims to bring together scholars,
16 practitioners and stakeholders to develop a responsive research agenda that identifies
17 challenges and innovative cost-effective and patient-centered solutions associated with
18 missed care. The project will also enable research and policy synergies by drawing out
19 the implications of missed nursing care across countries and identify innovative delivery
20 models and strategies with an overall aim to address patient needs. This study is part of
21 the project.

22
23 There are also some studies that brought evidence of care omissions and that nurses do
24 not provide all the necessary care to patients [22, 23,24, 25]. The main reasons for that
25 phenomenon was lack of resources and time, so nurses prioritize care, leading to some
26 processes to be delayed [22] or undone [26], or not completed[27, 28],or not delivered
27 according to quality protocol standards [29]. It has been demonstrated that missed

nursing care is an international and important phenomenon, which might take place more frequently, due to the fact that nurses are in continuous interactions with patients and they are called to response in the whole spectrum of patients' needs, in an extremely complex environment, taking multiple tasks at the same time. Although in the context of care impartiality is necessary, in exceptional circumstances a patient might be prioritized [30]. The prioritization process in relation with the existence of any connection between patient's integrity and health professional, omissions can be implied [30]. This fact indicates that nurses might dedicate more time/resources or prioritize the needs of a particular patient with more complex needs than another patient or reverse.

Two systematic reviews on missed nursing care [27, 31], have shown that communication, dental health, education, documentation, mobilization, supervision, update of care plan, personal care, the medication, preparation for discharge [27,33,34, 35,36, 37, 38,39], and psychological support [26] were the most frequent omissions by nurses. These studies have not indicated if missed nursing care was correlated with specific group of patients. A study [40] revealed that nurses prioritize care in the basis of age or mental impairment of the patient, resulting in discrimination of care for older people, as they come last, during prioritization process. Many studies have associated the quality of care and missed nursing care [19, 35, 41, 42, 43,44]. In addition patient safety, falls, immobility, dyspnea, incontinence [23, 41, 45, 46], pneumonia, urine infection, delirium [25, 26,47] and in hospital infections [26,41,45] have been proven as impact of the phenomenon on patients.

A systematic review [48] has identified the reasons for the low level of knowledge and negative attitudes and the beneficial action of intervention programs to nurses. The

establishment of a qualified program may increase knowledge and improve nursing attitudes, with the ultimate goal of reducing omissions and improving the quality of care provided to people with dementia. If knowledge and attitudes of nurses are associated with care failures, those two variables will be part of the reasons for the missed nursing care, but without marginalize the other factors (organizational, administrative, working environment, moral conflicts, inadequacy resources, etc.), already acknowledged.

METHOD AND ANALYSIS

Aim

This study aims to advance the level of knowledge, promote positive attitudes of nurses and reduce care deficits towards PwD through the implementation of a training program.

Specifically the aims are:

1. To explore the level of knowledge and nurses' attitudes towards the care of PwD.
2. To explore the care and care deficits of PwD, aiming to get more information about nurses' knowledge and attitudes, so as to strengthen the training program.
3. To implement a training program, in order to increase knowledge, improve attitudes and reduce missed care for patients with dementia

Design

This study is a mixed method study, consisting of three stages. Firstly, a descriptive study will take place, to evaluate the level of knowledge and attitudes of all acute hospital nurses, through the use of structured questionnaires. Secondly, an observation study will

be held in order to detect the kind of care that is provided in hospital settings towards PwD. Lastly, a quasi-experimental study will follow with one group of nurses, including one pre and two posttests. This will be accomplished by the implementation of a one-day training program to two groups of acute hospital nurses. Each group will consist of 20 nurses and the intervention will be specifically designed for increasing the knowledge and attitudes of nurses towards PwD. The reasons that quasi-experimental design was selected are due to the fact that there will not be a control group, and the participants cannot be randomly selected because they will need to participate in their free time.

Stage 1 Evaluation of the level of knowledge and the attitudes of nurses towards dementia care.

Through a systematic review of the literature, regarding knowledge and attitudes of nurses towards dementia care it has been revealed that knowledge was lacking and attitudes were non-favorable [48]. So, there is a possibility that the quality of dementia care is affected. In this stage two structured questionnaires will be used: 1) the Dementia Knowledge Assessment Tool Version 2 [50] for knowledge and 2) the Dementia Attitudes Scale [51], as far as it concerns attitudes. Both instruments were used in previous studies supporting their validity and reliability [50, 52, 53, 54]. The sample will include all nurses, working in acute hospital settings of the 5 main general hospitals of the country and provide care for PwD. Pediatric wards, outpatient clinic, emergency and maternity department will be excluded as they do not provide care to those patients, as frequent as others wards. Inclusion criteria are:

- Registered nurses based on the National law
- Working in any department of the hospital that provides care to PwD for at least one year
- Voluntary participation in study

Questionnaires will be completed anonymously and the aim of the study will be explained in the first page prior the questionnaires, along with the details for the contact person for further details. The completion of the questionnaires will be considered as the consent to participate. Questionnaires will be distributed by the researcher and returned to a closed box at the office of each ward in an envelope.

Dementia Knowledge Assessment Tool Version 2

The first part of both questionnaires will include demographic information. The Dementia Knowledge Assessment Tool Version 2 (DKAT) [50] is used to measure the knowledge of nurses and caregivers about dementia and was designed exclusively for these groups [52]. It contains 21 *correct / wrong /not know* answers for assessing knowledge regarding causes, risk factors, disease symptomatology, care, impact, evaluation and management. The correct answers range from 0-21, with the highest score indicating more knowledge. It has been used by other researchers [50,52] and it is a valid and reliable tool (Cronbach's alpha = 0.79) [50].

Dementia Attitude Scale

The Dementia Attitude Scale (DAS) [51] was designed to investigate nurses' attitudes towards PwD. It is divided into a seven-level Likert scale of 20 questions, which reflects the behavioral and cognitive components of nursing attitudes towards PwD [5]. It

contains two factors (a) knowledge (b) attitudes with accepted reliability (Cronbach's alpha 0.83-0.85) [51] and validity ($r=0.96$) [51] in correlation with similar instruments [54]. Its development was based on the three-dimensional attitude model that defines three components: influence, behavior and knowledge [55]. Probable scores range from 20-140 with the highest score indicating more positive attitude [53]. It has been used in previous surveys [51, 53, 54] and is a commonly accepted and reliable measurement tool.

For the data analysis inferential analysis will be reported such as linear regression and parametric measures (t-test, ANOVA, confidence intervals and correlation coefficients Pearson) as needed and descriptive (mean, standard deviation, median, frequencies). Sociodemographic correlates will be assessed in correlation with the level of knowledge and attitudes. Considering data analysis for the Dementia Knowledge Assessment Tool version 2, descriptive statistic will be used and multiple regression analysis. This analysis will be followed to control confounder factors that might influence variables. For Dementia Attitude Scale, non-parametric test and test Wilcoxon will take place. All the analysis will be performed by SPSS 22.0. Multiple imputations will take place in order to handle missing data.

Both the questionnaires will be translated and back translated according to the guidelines suggested by WHO, 2016 [56] and the validation will include a test - re-test, Cronbach's alpha and a factor analysis. Translation process will include forward translation, then expert panel for backward translation, a pre-testing and cognitive interviewing, until we reach the final version. This procedure will be done during the pilot phase of the study that will include a sample of 100 nurses working in the emergency departments across the country. Those 100 nurses will be included only for the pilot study and not for the main

study. As nurses from the emergency department are not included in the main study, pilot study was selected to take place among this group of nurses. Furthermore, nurses working in emergency departments do not provide care to PwD more than one day, although PwD visit the particular department in frequent occasions. So, we concluded that is interesting to investigate emergency department nurses' level of knowledge and attitudes, considering the frequent, but short term visit of PwD to the department.

Stage 2 observation study to detect any missed nursing care towards PwD

Data from the observational study will be collected through field notes, in order to investigate care provided to PwD, based on the hypothesis that if nurses' knowledge is low and their attitudes are negative, there is the possibility that care is not up to the expected quality standards. These data are expected to give more information as to the care of PwD and especially care deficits, care omissions and missed care, aiming to strengthen the training program and focus on specific issues that will facilitate the care delivered to this group of patients. We have conducted a scoping review considering the methodology of observational study, so as to proceed with our design [57-63]. The observer will be the main researcher, which is a nurse. One week training and one week pilot study will precede the main study. Pilot study will include the determination and familiarization with the environment, the data collection process and co-ordination with the observation timetable [64]. Field notes will not include any characteristic of patient or nurses.

a) Sample

The sample will include PwD, who are hospitalized for any reason. The sample strategy in observational studies is purposeful sampling, since the particular research topic is investigated in a pre-determined population. A patient will be observed for one shift daily (morning or evening). The night shift has been excluded, due to its uneven duration which is 12 hours compared to the 6-hours shift (morning-evening). The sample size will be determined by the data saturation criterion.

In qualitative methods, the sample is smaller and when the data renewal no longer exists, the collection process is considered adequate [65]. Inclusion criteria will be the diagnosis of dementia [66-68] and the hospitalization of the person with dementia, regardless of the reasons. The researcher will be informed at the beginning of the shift by the departmental officer if PwD are hospitalized in the department. The researcher will ensure and manage confidentially the data and diagnosis and cannot use them for the purposes of any other research. In the case of more than one patient per ward, random sampling will be performed, and data will be collected for one patient at a time and then the patient will not be included again in the sample.

b) Duration of observation

The duration of the observational study will last 1 day per patient. If there is availability of patients the data collection process will last 10-12 days. In other case the process will last until we reach 10 patients, with the maximum duration one month [57, 60, 62, 63, 69].

(c) Wards

The departments that are going to be observed are Medical and Orthopedic. The specific sections of the hospital were selected on the basis of the Alzheimer's Society report [21], 2009, which showed that 14% of patients with dementia were admitted to hospital after falls, 12% for hip replacement, 9% for urinary tract infection, 7% for respiratory infection and 7% due to stroke. In addition, another study [70] added to the above mentioned reasons dehydration, as well.

The observer will stay in patients' room, not wearing a nurse uniform, preserving at least 3 meters distance from the patients' bed [64, 71] and record everything she sees in the context of care in her field notes. This distance is probably predetermined for respect patient's privacy. The observer will not participate in any intervention or error in order not to influence the result of the study and the normal process of the department, with only exception if is a life or death issue. Additionally, no communication will take place with nurses, patients, or patients' relatives during observer stay. Each patient will be recorded in new field notes.

d) Field notes

Data collection in the observational study will be based on field notes written by the observer, during her stay to patient's room. The notes will be "methodological", "descriptive" and "theoretical". Descriptive field notes will include information about anything the observer watch or hear, regarding communication among nurses-patient, process and environment characteristics [72, 73]. Methodological field notes will be comprised of the technique of data collection. In particular, those notes include the process that the observer will use to write down the data, for instance the adjustment of

the observer in the culture of the organization [72]. Theoretical field notes regard the conscious, controlled efforts of the researcher to come to the essence of her notes. Those notes are the personal interpretation of data by the observer [73]. More specifically, the researcher tries to understand behaviors or processes and to document some ideas, questions, thoughts or concerns as a reflection of her data [102]. Only the research team will be aware of the context of the field notes, so as not to influence the results of the study and remain the confidentiality and anonymity of the participants. Data will be coded and categorized, so content analysis will follow. As content analysis is a reflective process [74] the identification and condensation of the meaning units, the coding and the categorization into themes is going to be a repeated event, by at least two of the research team, in order to maintain the quality and the trustworthiness of the analysis [75].

Stage 3 Quasi-experimental study

Once the descriptive and observation study have been completed, a quasi-experimental study with one group and one pre and two post tests will follow. This part of the study will include the organizing of a one day training course, which will facilitate nurses to provide a better and consistent care to PwD. The training will consist of various topics and will be conducted by dementia experts in order to describe, the pathophysiology of the disease and the appropriate care for needed for these patients. The study has no costs, as the experts are willing to participate in the course free of charge. Furthermore, no economic outcomes are expected to emerge through the particular stage of the study.

The systematic review of the literature [48] considering intervention studies to nurses has detected eleven educational programs [5, 53, 76-84] with a large variety on designs. Most

of them were seminars [77-84] lasting from 7 hours [77, 79], 1 day [81, 84], 3 days[78] to 15 weeks[83].

Other studies used one day workshops [76, 80], whilst another research team used a one day online seminar [53] or educational video [82]. This fact could be attributed to the deficiency of an established and validated program, so each research team created its own program for the purpose of each research.

For the purpose of the present study we have selected the “Getting to Know me” program (with the approval of the authors) [79], as it has checked validity and reliability but also it has been applied in more than one studies [79] and it has been adopted by the NHS.

The creators suggest that the program can be applied to other countries, as well, as the results were beneficial for acute hospital nurses. However it is expected that after the observational study, some modifications will be necessary to be introduced in order to focus on minimizing missed care.

a) Description of the program

This program is specifically designed for acute hospital nurses that provide care to PwD. It includes lectures, video, a guide for communication skills, the form “Getting to know me” and a 30 pages book. The main topics of lectures are introduction to dementia, holistic care, communication, impact of hospital environment, person centered-care and management of aggressive behavior. The program is going to be translated to Greek and some modifications will take place, so as to respond to study sample’s needs and to the findings derived from the observation study. The modification will be an addition of an experiential workshop and participants will have more interaction through role play. The

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program will be implemented in two days and the sample will be twenty nurses per day, total number forty nurses.

As the program includes many interaction exercises the suggested candidate's number by the creators of the program, is up to twenty. The sample size was calculated based on previous intervention studies [5, 56, 79, 81, 83]. Inclusion criteria will be the same as the descriptive stage of the study, however priority will be given to nurses who work most with PwD, such us medical, orthopedic or surgical wards.

b) Evaluations

Three evaluations will include a) prior the implementation of the program, b) immediately after the intervention c) the last one will take place three months after the intervention [77, 78, 84-87] in order to see if the effect of the program remains for a longer period. The research team will be responsible for organizing, enrollment and coordinating the training course and the participation of nurses will be volunteering. If more than forty nurses are willing to take part random sampling will be followed. A certification will be given after the completion of the last questionnaires to those who participate, in order to increase interest for joining the training course. Data from the three stages are going to be storage in the researcher's office, where no one but the researcher is allowed entry. Data monitoring will be performed by the supervising committee and the PhD candidate will be responsible for analyzing, coding and writing the data. Furthermore, the committee will conduct range checks of the values as far as it concerns the questionnaires. Regarding the observational data two members of the

committee will separately proceed to the coding process and then a discussion will follow with the PhD candidate, in order to develop thematic analysis.

The main outcomes of the study are the level of knowledge and attitudes of nurses towards the care of PwD and secondary outcomes include minimizing missed care.

The study progress is on the stage of the pilot study, which is expected to finalize until 20th of April 2019. The instruments translation has been done, during September-January 2019. The first results are expected on 1st of July 2019 from the descriptive stage and until 30th of September 2019 the qualitative findings will be available. Data from the third stage are expected between 10th -17th of February 2020, since the intervention is programmed to be implemented on 19th of September 2019 and the last data that are going to be collected are three months after the intervention. The timeline of the study is illustrated on Figure 1.

Patient and Public Involvement

During the second stage of the study patients and their carer participation is of high importance, by consenting to being observed. If there are not willing to do so, the study design for stage two will not be achievable. Research questions were informed based on published literature regarding carers' experience during hospitalization of PwD [21]. Also, informing them that care process is going to be observed they will share with us their priorities and their opinion about hospital care, so the outcome will be on stage three, as we will update our training program based on carers' experience.

After the observer will be informed about the rooms that hospice PwD, she will be responsible for the recruitment of the patients and their carers. She will explain the aim,

the design and the volunteer nature of the study, along with contact details for all the research team. If they agree, they will sign a consent form and the data collection will start. Also, they will be informed that study results will be available in lectures that the researchers make in cooperation with the national Alzheimer Society. In cases that are not able to participate they can contact a member of the research team and inform them about the results of the study.

ETHICS AND DISSEMINATION

The protocol was approved by Cyprus National Bioethics committee (EEBK: 2018.01.02) and by the Research committee of the ministry of health. Access to the field of research was obtained by each hospital manager and the managers of each ward. The relatives of patients with dementia will be informed that patients will be observed and the aims of the study will be explained, so as to gain their permission.

The anonymity, the trustworthiness and the process of the collected data will also be explained in the consent form both for the nurses and well as the relatives of PwD, that the data are going to be used only for the purpose of the particular study and when is finished are going to be destroyed.

In order to remain the confidentiality and the anonymity of the participants none of the patients' or the nurses' identification will be included. Patients are going to be coded and no one except from the main researcher will be able to know to whom the data are referred. The research team will be the only who will have access to data. If any important modification of the protocol will take place all the relevant parties will be

informed (Ethics Committee, Health Ministry). This study is in conjunction with the SPIRIT statement.

Dissemination strategy includes presentations in international and national scientific conferences. More emphasis will be given in nursing conferences, as the audience will be more benefited in clinical practice. All the results are going to be submitted in peer-reviewed journals for publication. Moreover, the results of the intervention stage are going to be presented in policy makers in order the program to be implemented in a broader population of nurses. The results of the study are going to inform future study, as well, targeting carers of PwD and evaluate if the usefulness is as important as to nurses.

Author statement

Authors' contributions: ME has written the manuscript. EP supervised the writing process, reviewed the manuscript and consulted the first author. AM and AC have reviewed and contributed in writing the manuscript.

Funding: The research is supported by Leventis foundation grant number EPI009/181120/820750. Publication fees were granted by the Cyprus University of Technology Open Access Author Fund.

Competing interests: The authors declare that they have no competing interests.

Acknowledgements: The authors gratefully acknowledge nurses and departmental officers for their cooperation and the permission to conduct the observation study to their wards.

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References

1. Alzheimer’s Association. Alzheimer’s disease facts and figures. 2016. Available at: http://www.alz.org/documents_custom/2016-Facts-and-Figures-Fact-Sheet.pdf. Accessed 19 March 2019.
2. WHO. Dementia: a public health priority. 2012. Available at: http://www.who.int/mental_health/publications/dementia_report_2012/en/. Accessed 14 February 2019.
3. Knapp M. Economic outcomes and levers: impacts for individuals and society. *IntPsychogeriatr*. 2007;19(3):483-95.
4. Robinson A, Eccleston C, Annear M, Elliott K.E, Andrews S, Stirling C, Ashby M, Donohue C, Banks S, Toye C. &McInerney F. Who knows, who cares? Dementia knowledge among nurses, care workers, and family members of people living with dementia. *JournalofPalliativeCare*.2014; 30(3):158–165.
5. Bryans M, Keady J, Turner S, Wilcock J, Downs M &Iliffe S. An exploratory survey into primary care nurses and dementia care. *British Journal of Nursing*.2003;12(17):1029–1037.

6. Kada S, Nygaard H.A, Mukesh B.N &Geitung J.T. Staff attitudes towards institutionalized dementia residents. *Journal of Clinical Nursing*.2009;18(16): 2383–2392.
7. Josefsson K, Sonde L &Wahlin T.-B.R. Competence development of registered nurses in municipal elderly care in Sweden: a questionnaire survey. *International Journal of Nursing Studies*.2008;45(3):428–441.
8. Galvin J.E, Kuntemeier B, Al-Hammadi N, Germino J, Murphy-White M & McGillick J. “Dementia-friendly hospitals. *Alzheimer Disease & Associated Disorders*.2010;24(4):372–379.
9. Marx K.A, Stanley I.H, Van Haisma K, Moody J, Alonzi D, Hansen B.R &Gitlin L.N. Knowing versus doing: Education and training needs of staff in a chronic care hospital unit for individuals with Dementia. *Journal of Gerontological Nursing*.2014;40(12):26–34.
10. Barrett J.J., Haley W.E., Harrell L.E. & Powers R.E. Knowledge about Alzheimer disease among primary care physicians, psychologists, nurses, and social workers. *Alzheimer Disease & Associated Disorders*.1997;11(2):99–106.
11. WHO. Management of substance abuse. Process of translation and adaption of intruments.2016.
http://www.who.int/substance_abuse/research_tools/translation/en/. Accessed 13th March 2019.
12. International Federation if Red Cross and Red Crescent Societies (IFRC). What is vulnerability?. 2014. <http://www.ifrc.org/en/what-we-do/disaster->

- [management/about-disasters/what-is-a-disaster/what-is-vulnerability/](#). Accessed 21th January 2019.
13. Centers for Disease Control and Prevention (CDC). Elder abuse: prevention Strategies. 2009.
<https://www.cdc.gov/violenceprevention/elderabuse/prevention.html> . Accessed 3rd January 2019.
14. Centers for Disease Control and Prevention (CDC). Elder Abuse. 2017.
<https://www.cdc.gov/violenceprevention/elderabuse/index.html>. Accessed 3rd January 2019.
15. Dixon J, Manthorpe J, Biggs S, Mowlam A, Tennant R., Tinker A&McCreadie C. Defining elder mistreatment: Reflections on the United Kingdom study of abuse and neglect of older people. *Ageing & Society*.2010;30(3)403–420.
16. Gilhooly M.L.M, Cairns D, Davies M, Harries P, Gilhooly K.J, Notley E. Framing the detection of financial elder abuse as bystander intervention: Decision cues, pathways to detection and barriers to action. *Journal of Adult Protection*.2013;15(2):54–68.
17. Manthorpe J. Elder abuse. In: Dening. Oxford textbook of old age psychiatry (2nd ed.), Oxford: Oxford University Press. 2013. p.779-83.
18. Manthorpe J. The abuse, neglect and mistreatment of older people with dementia in care home and hospitals in England: the potential for secondary data analysis: innovative practice. *Dementia*.2015;14(2):273-9.
19. Skirbekk H. & Nortvedt P. Making a difference: A qualitative study on care and priority setting in health care. *Health Care Analysis*.2011;19(1):77–88.

20. Boyle M, Williams B, Tedd B, Molloy A. et al. Attitudes of undergraduate health science students towards patients with intellectual disability, substance abuse, and acute mental illness: a cross-sectional study. *BMC Medical Education*. 2010. <https://bmcmmededuc.biomedcentral.com/articles/10.1186/1472-6920-10-71>. Accessed 22th February 2019.
21. Alzheimer Society. Counting the cost. 2009. https://www.alzheimers.org.uk/download/downloads/id/787/counting_the_cost.pdf. Accessed 9th February 2019.
22. Kalisch B.J, Landstrom G.L. & Hinshaw A.S. Missed nursing care: A concept analysis. *Journal of Advanced Nursing*. 2009;65(7):1509–1517.
23. Kalisch B, Tschannen D, Lee H, Friese C. Hospital variation in missed nursing care. *Am J Med Qual*. 2012;26(4):291–299.
24. Papastavrou E. The ethics of care rationing within the current socioeconomic constraints. *Health Science Journal*. 2012;6(3):362–364.
25. Ball J, Griffiths P, Rafferty A.M., Lindqvist R, Murrels T. QUANTITATIVE A cross-sectional study of ‘care left undone’ on nursing shifts in hospitals. *J of Adv Nurs*. 2016;72(9):2086-97.
26. Schubert M, Carke S, Glass T, Schaffert-Witvliet B, De Geest S. Identifying thresholds for relationship between impacts of rationing of nursing care and nurse and patient reported Outcomes in Swiss hospitals : A correlational study. *Int J Nurs Stud*. 2010; 46(7):884–893.

27. Papastavrou E, Andreou P, Efstathiou G. Rationing of nursing care and nurses-patient outcomes: a systematic review of quantitative studies. *Int J Health Manage.*2014;2(1):3-25.

28. Verall C, Aberly E, Harvey C, Henderson J, Willis E, Hamilton P, Toffoli L, Blackmann I. Nurses and midwives perceptions of missed nursing care--A South Australian study. *Collegian.*2015;22(4).413-20.

29. Blackman I. Factors influencing why nursing care is missed. *Journal of Clinical Nursing.*2015;24(1-2):47-56.

30. Nortvedt P, Hem M.H. & Skirbekk H. The ethics of care: Role obligations and moderate partiality in health care. *Nursing ethics.*2011;18(2):192-200.

31. Jones T, Hamilton P, Murry N. Unfinished nursing care, missed care and implicitly rationed care: state of the science review. *Int J of Nursing Studies.*2015;52(6):1121-37.

32. Bail K, Berry H, Grealish L, Draper B, Karmel R, Gibson D. &Peut A. Potentially preventable complications of urinary tract infections, pressure areas, pneumonia, and delirium in hospitalised dementia patients: Retrospective cohort study. *BMJ Open.*2013;3:6.

33. Kalisch BJ, Xie B, Dabney BW. Patient-reported missed nursing care correlated with adverse events. *Am J Med Qual.*2014;29:415-22.

34. Kalisch BJ, Tschannen D, Lee KH. Missed nursing care, staffing, and patient falls. *J NursCare Qual.*2012;27:6-12

35. Lucero R. Nursing Informatics Implications from a Study of Unmet Nursing Care Needs. *Connecting Health and Humans.*2009;5043:817-821.

36. Aiken LH, Sloane D, Griffiths P For the RN4CAST Consortium, et al. Nursing skill mix in European hospitals: cross-sectional study of the association with mortality, patient ratings, and quality of care. *BMJ Qual Saf*.2017;26:559-568.
37. Morin D, Leblanc N. Less money, less care: how nurses in long-term care allocate hours of needed care in a context of chronic shortage. *Int J Nurs Pract*.2005;11(5):214–220.
38. Kalisch B.J, Xie B. Errors of omission: missed nursing care. *Western J. Nurs. Res*.2014;36(7): 875–890.
39. Knopp-Sihota JA, Niehaus L, Squires JE,Norton PG, Estabrooks CA. Factors associated with rushed and missed resident care in western Canada nursing homes: a cross-sectional survey of health care aides. *J Clin Nurs*.2015;24:1815-25.
40. Pedersen R,Nortvedt P, Nordhaug M, Slettebo A, Grothe KH et al. In quest of justice? Clinical prioritisation in healthcare for the aged. *Journal of medical ethics*.2008;34(4):230–5.
41. Schubert M, Glass TR, Clarke SP, Schaffert-Witvliet B, De Geest S. Validation of the basel extent of rationing of nursing care instrument.*Nurs Res*.2007;55(6):416–424.
42. Sochalski J. Is more better?: the relationship between nurse staffing and the quality of nursing care in hospitals. *Med Care*.2004;42(2):II-67–II-73.
43. Ausserhofer D, Schubert M, Desmedt M, Blegen M.A., De Geest S., Schwendimann R. The association of patient safety climate and nurse-related organizational factors with selected patient outcomes: a cross-sectional survey. *Int. J. Nurs. Stud*.2013;50(2):240–252.

44. Ausserhofer D, Zander B, Busse R, Schubert M, De Geest S, Rafferty A.M, et al. Prevalence, patterns and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. *Br. Med. J. Qual. Safety*.2014;23(2):126– 135.

45. Lucero R.J, Lake E.T, Aiken L.H. Nursing care quality and adverse events in US hospitals. *J. Clin. Nurs*.2010;19(15–16):2185–2195.

46. Hayward R.A, Asch S.M, Hogan M.M, Hofer T.P, Kerr E.A. Sins of omission: getting too little medical care may be the greatest threat to patient safety.*J.Gen. Intern. Med*.2005;20:686–691.

47. Brown P, Fraser K, Wong CA, Muise M, Cummings G. Factors influencing intentions to stay and retention of nurse managers: a systematic review. *J NursManag*.2012; DOI: 10.1111/j.1365-2834.2012.01352.x

48. Evripidou M, Charalambous A, Middleton N, Papastavrou E. Nurses’ knowledge and attitudes about dementia care: systematic literature review. *PerspectivPsychiatr Care* 2018.Doi: 10.1111/ppc.12291.

49. Dhaini SR, Zúñiga F, Ausserhofer D, Simon M, Kunz R, De Geest S, Schwendimann R. Care workers health in Swiss nursing homes and its association with psychosocial work environment: A cross-sectional study. *Int J Nurs Stud*.2016;53:105-15.

50. Toye C, Lester L, Popescu A, McInerney F, Andrews S, Robinson AL. Dementia Knowledge Assessment Tool Version Two: development of a tool to inform preparation for care planning and delivery in families and care staff.*Dementia* (London).2014;13(2):248-56.

- 1
2
3 51. O'Connor M, McFadden S. Development and Psychometric Validation of
4 Dementia Attitude Scale. *Int J of Alzheimer*
5
6 *Disease*.2010.doi: 10.4061/2010/454218.
7
8
9
- 10 52. Robinson A, Eccleston C, Annear M, Elliott K.E, Andrews S, Stirling C, Ashby
11 M, Donohue C, Banks S, Toye C. &McInerney F. Who knows, who cares?
12 Dementia knowledge among nurses, care workers, and family members of people
13 living with dementia. *Journal of Palliative Care*.2014;30(3):158–165.
14
15
16
17
18
- 19 53. Kimzey M, Matel-Smith B, Alfred D. The impact of educational experiences on
20 nursing students' knowledge and attitudes toward people with Alzheimer's
21 disease: A mixed method study. *Nurse Education Today*.2016;46:57-63.
22
23
24
25
- 26 54. Scerri A, Scerri C. Nursing students' knowledge and attitudes towards dementia-
27 a questionnaire survey. *Nurse Education Today*.2012;33(9):962-8.
28
29
30
- 31 55. Breckler S.J. "Empirical validation of affect, behavior, and cognition as distinct
32 components of attitude". *Journal of Personality and Social Psychology*.1984;
33 47(6):1191–1205.
34
35
36
37
- 38 56. WHO. Management of substance abuse. Process of translation and adaption of
39 instruments.2016.
40
41
42 http://www.who.int/substance_abuse/research_tools/translation/en/. Accessed 13th
43
44 September 2018.
45
46
- 47 57. Välimäki T, Vehviläinen-Julkunen K, Pietilä AM. Diaries as research data in a
48 study on family caregivers of people with Alzheimer's disease: methodological
49 issues. *J AdvNurs*.2007;59(1):68-76.
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 58. Ballermann MA, Shaw NT, Mayes DC, Gibney RT, Westbrook JI. Validation of
4 the Work Observation Method By Activity Timing (WOMBAT) method of
5 conducting time-motion observations in critical care settings: an
6 observational study. *BMC Med Inform Decis Mak*.2011;17:11:32.
7
8
9
10
11
12 59. Jackson D, Wilkes L, Luck L. Cues that predict violence in the hospital setting:
13 findings from an observational study. *Collegian*.2014;21(1):65-70.
14
15
16
17 60. D'Antonio S, Bagnasco A, Bonetti L, Sasso L. Observation study on interruptions
18 during nurses work in two surgical wards of a hospital in Liguria. *Prof*
19 *Inferm*.2014;67(4):211-8.
20
21
22
23
24 61. Clisset P, Porock D, Harwood RH, Gladman JR. The response of healthcare
25 professionals to the admission of people with cognitive impairment to acute
26 hospital setting: an observation and interview study. *J Clin Nurs*.2014;23(13-
27 14):1820-9.
28
29
30
31
32
33 62. Hoviattalab K, HashemizadehH,Cruz G, Halfens Ruud J G, Dassen T. Nursing
34 practice in the prevention of pressure ulcers : An observational study of German
35 Hospitals Nursing practice in the prevention of pressure ulcers : an observational
36 study of German Hospitals. *J Clin Nurs*.2015;11-12:1513-24.
37
38
39
40
41
42 63. Tan Y, Wai T, Sim C,I Ng. Optimising peripheral venous catheter usage in the
43 general inpatient ward : a prospective observational study. *J Clin*
44 *Nurs*.2016;26:133-39.
45
46
47
48
49 64. Cohen L, Manion L, & Morrison K. Research methods in education. London,
50 Routledge.2007.
51
52
53
54 65. Marshall M. Sampling for qualitative research. *Family Practice*.1996;13(6):5225.
55
56
57
58
59
60

66. Streit S, Limacher A, Zeller A, Burrge M. D. Detecting dementia in patients with normal neuropsychological screening by Short Smell Test and Palmo-Mental Reflex Test: an observational study. *BMC Geriatrics*.2015;15:90.
67. Travers C, Byrne G.J, Pachana NA, Klein K, Gray LC. Prospective observational study of dementia in older patients admitted to acute hospitals. *Australas J Ageing*.2014;33(1):55-8.
68. Hager K, Calabrese P, Frolich L, Gobel C, Berer FM. An observational clinical study of the efficacy and tolerability of donepezil in the treatment of Alzheimer's disease. *Dement GeriatrCogn Disord*.2003;15(4):189-98.
69. Goudra B, Singh P.M,Galvin E. Comparison of Compliance of Glove Use Among Anesthesia Providers: A Prospective Blinded Observational Study. *AANA Journal*.2014; 82(5):363-67.
70. Natalwala A, Potluri R, Uppal H, Heun R. Reasons for hospital admissions in dementia patients in Birmingham, UK, during 2002-2007.*Dementia GeriatrCogn Disord*.2008;26(6):499-505.
71. Creswell J, Vicki L, Plano C. Designing and conducting mixed method research. Los Angeles: SAGE Publications. 2011.
72. Bernard H.R. Research methods in anthropology: Qualitative and quantitative approaches. Lanham, MD: AltaMira Press.2011.
73. Lonner W.G, Berry J.W. Field notes in cross-cultural research. Newbury Park.CA: Sage Publications. 1986.
74. Erlingsson G, Brysiewicz P. A hands-on guide to doing content analysis. *African Journal of Emergency Medicine*.2017;7(3):93-99.

75. Bengtsson M. How to plan and perform a qualitative study using content analysis. *Nursing plan open*.2016;2:8-14.
76. Kang Y, Moyle W, Venturato L. Korean nurses' attitudes towards older people with dementia in acute care settings. *International Journal of Older People Nursing*.2011;6(2):143-152.
77. Galvin J.E, Kuntemeier B, Al-Hammadi N, Germino J, Murphy-White M. &McGillick J. "Dementia-friendly hospitals. *Alzheimer Disease & Associated Disorders*.2010;24(4):372–379.
78. Surr C.A, Smith S.J, Crossland J. & Robins J. Impact of a person-centred dementia care training programme on hospital staff attitudes, role efficacy and perceptions of caring for people with dementia: a repeated measures study. *International Journal of Nursing Studies*.2015;53:144–151.
79. Elvish R, Burrow S, Cawley R, Harney K, Graham P, Pilling M, Gregory J, Roach P, Fossey J. & Keady J. 'Getting to know me': the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & Mental Health*.2014;18(4):481–488.
80. Manthorpe J, Iliffe S. & Eden A. Early recognition of dementia by nurses. *Journal of Advanced Nursing*.2003;44(2):183–191.
81. Davison T.E, McCabe M.P, Visser S, Hudgson C, Buchanan G. & George K. Controlled trial of dementia training with a peer support group for aged care staff. *International Journal of Geriatric Psychiatry*.2007;22(9):868–873.

82. EinangAlnes R, Kirkevold M. &Skovdahl K. Insights gained through MarteMeo counselling: experiences of nurses in dementia specific care units. *International Journal of Older People Nursing*.2011;6(2):123–132.
83. McCaffrey R, Tappen R.M, Lichtstein D.M. &Friedland M. Interprofessional education in community-based Alzheimer’s disease diagnosis and treatment. *Journal of Interprofessional Care*.2013;27(6):1356–1820.
84. Palmer J.L, Lach H.W, McGillick J, Murphy-White M, Carroll M.B. & Armstrong J.L. The dementia friendly hospital initiative education program for acute care nurses and staff. *The Journal of Continuing Education in Nursing*.2014;45(9):416–424.
85. Gustafsson M, Bohman DM, Borglin G. Challenges of conducting experimental studies within a clinical nursing context. *ApplNurs Res*.2014;27(2):133-6.
86. Borglin G, Gustafsson M, Krona H. A theory-based educational intervention targeting nurses' attitudes and knowledge concerning cancer-related pain management: a study protocol of a quasi-experimental design. *BMC Health Serv Res*.2011;23(11):233.
87. Mahedran R, Tan J,Griva K, Lim H, Ng H.Y, Chua J,Lim, SE and Kua EH. A pilot, quasi-experimental, mixed methods investigation into the efficacy of a group psychotherapy intervention for caregivers of outpatients with cancer: the COPE study protocol. *BMJ Open*.2015; 5(11):e008527.
88. Papastavrou E, Charalambous A, Vryonides S, Eleftheriou C, Merkouris A. To what extent are patients' needs met on oncology units? The phenomenon of carer rationing. *Eur J Oncol Nurs*.2016;21:48-56.

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41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

89. Chassin M.R, Galvin R.W. The National Roundtable on Health Care Quality. The urgent need to improve health care quality: Institute of Medicine National Roundtable on Health Care Quality. *J. Am. Med. Assoc.*1998;280(11):1000–1005

90. El-Jardali F, Lagace’ M. Making hospital care safer and better: the structure–process connection leading to adverse events. *Healthc. Q.*2005;8(2):40–48

91. Halvorsen K, Slettebø A, Nortvedt P, Pedersen R, Kirkevold M, Nordhaug M, Brinchmann BS. Priority dilemmas in dialysis – The impact of old age Priority dilemmas in dialysis : the impact of old age. *J Med ehics.*2008;34(8):585-9.

92. Tschannen D, Kalisch BJ, Lee KH. Missed nursing care: the impact on intention to leave and turnover. *Can J Nurs Res.*2010;42(4):22–39

93. Castner J, Wu Y.W.B, Dean-Baar S. Multi-level model of missed nursing care in the context of hospital merger. *Western J. Nurs.Res.*2014.
<http://dx.doi.org/10.1177/0193945914535670> Accessed 11th January 2019.

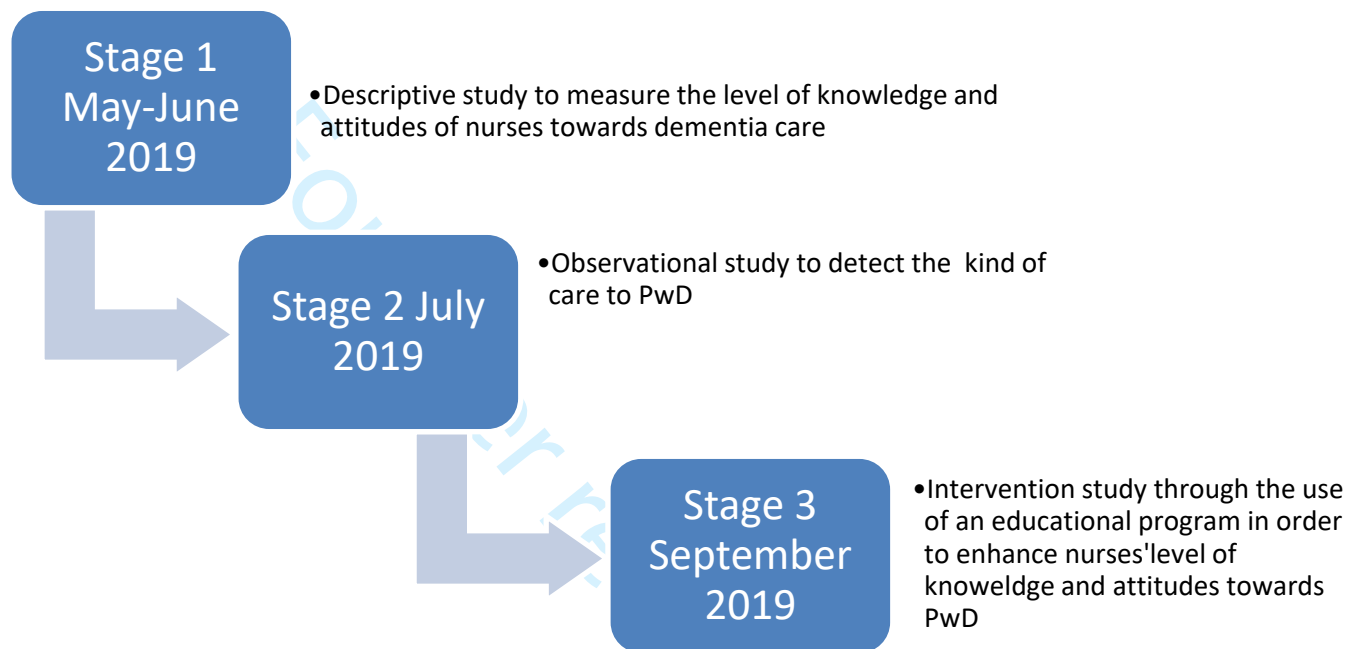
94. Williams J. Care quality Commission Dignity and nutrition inspection program: National overview.2011.https://www.cqc.org.uk/sites/default/files/documents/20111007_dignity_and_nutrition_inspection_report_final_update.pdf Acceded 1st October 2018.

95. McWhirter JP, Pennington CR. Incidence and recognition of malnutrition in hospital. *BMJ.*1994;308(6934):945-8.

96. Rochefort CM, Clarke S. Nurses' work environments, care rationing, job outcomes, and quality of care on neonatal units. *J Adv Nurs*.2010;66(10):2213–2224.
97. Vryonides S, Papastavrou E. & Charalambous A. The ethical dimension of nursing care rationing : A thematic synthesis of qualitative studies. *Nursing Ethics*.2015;22(311):881–900.
98. Vryonides S, Papastavrou E, Charalambous A, Andreou P, Eleftheriou C, Merkouris A. Ethical climate and missed nursing care in cancer care units. *Nurs Ethics*.2016;27.pii:0969733016664979.
99. Kalisch BJ. Missed nursing care: a qualitative study. *J Nurs Care Qual*.2006;21(4):306–313.
100. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *AnnIntern Med*.2013;158:200-207.
101. Bail K, Grealish L.'Failure to Maintain': A theoretical proposition for a new quality indicator of nurse care rationing for complex older people in hospital. *Int J Nurs Stud*.2016;63:146-161.
102. Montgomery P & H Bailey, P. Field Notes and Theoretical Memos in Grounded Theory. *Western journal of nursing research*. 2007;29:65-79.

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For peer review only





SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Check
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	35
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 35
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	8

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	N/A
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	17-18
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	18
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	17
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	19
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14, 17

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	18
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	18
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	18
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	18
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11,15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18-19

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18-19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	21
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14,16,20, 21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	35
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	35
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	11, 20
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

BMJ Open

Implementation of a training program to increase knowledge, improve attitudes and reduce nursing care omissions towards patients with dementia in hospital settings: a mixed method study protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030459.R1
Article Type:	Protocol
Date Submitted by the Author:	28-May-2019
Complete List of Authors:	Evripidou, Melina; Cyprus University of Technology, Nursing Merkouris, Anastasios; Cyprus University of Technology Faculty of Health Sciences, Nursing, School of Health Sciences Charalambous, Andreas; Cyprus University of Technology; Turun Yliopisto, Nursing Papastavrou, Evridiki; Cyprus University of Technology, nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Ethics, Nursing
Keywords:	Rationing < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL ETHICS, MEDICAL EDUCATION & TRAINING, Dementia < NEUROLOGY

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Implementation of a training program to increase knowledge, improve attitudes and reduce nursing care omissions towards patients with dementia in hospital settings: a mixed method study protocol.

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Keywords: *nurses, dementia, knowledge, attitudes, care*

Word counts: 7686

ABSTRACT

Introduction: There is evidence showing that when nurses have to allocate their time because of a lack of resources, older patients and especially those with dementia have a secondary care priority. The purpose of this study is to advance the level of knowledge, promote positive attitudes of nurses and reduce care deficits towards PwD through the implementation of a training program. The program will be enriched by an observational study of the care of patients with dementia to identify areas of missed care.

Method and analysis: This study will follow a mixed methodology consisting of three stages; 1) evaluation of the level of nurses' knowledge and attitudes towards dementia care through the use of structured questionnaires, 2) observational study to evaluate nursing care in hospital settings, in order to detect any missed care, 3) quasi-experimental study, with a before and after design, through the implementation of the training program in order to increase nurses' knowledge, improve attitudes and consequently to promote care for patients with dementia. The data will be analyzed with descriptive and inferential statistics with the use of the SPSS 24.0 and with content analysis as regards to the observational data.

Ethics and dissemination: The protocol was approved by the National Bioethics committee and other local committees (EEBK: 2018.01.02). The participants will give their informed consent and the anonymity and confidentiality. Also, the protection of data will be respected. The results of the study will be disseminated in peer-reviewed international journals and conferences. If the intervention is successful, the training package will be given to the Continuous education unit of the National Professional Association in order to be used on a regular basis.

Article summary

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Strengths of the study

- The main strength of the study lies in the fact that missed care that is mainly measured through self-reporting instruments, will be detected through observation, increasing the innovation of the methodological approach of the problem.
- The educational intervention will not only focus on dementia knowledge deficiency, but it will also address specific areas of missed care for patients with dementia.

Limitations of the study

- The intervention will last for only one day and it is not certain that the effects will last for a long time, meaning that there will be a need to repeat educational interventions at a later stage.

INTRODUCTION

People with dementia (PwD) occupy 25% of hospital beds [1] and this number is expected to triple by 2050, considering the rapid epidemiological increment of the disease [2]. This group of patients is characterized by cognitive impairment placing them in an unfavorable position to demand the best possible care like other patients [3]. Consequently they might be in great danger of neglect. The increase in life expectancy associated with the multidimensional problem of dementia, inevitably leads to the need of investigating this topic. WHO 2017 [2], has highlighted the importance of the problem about dementia care in a global action plan on the public health response to dementia and set as a target 75% of countries to develop national policies, plans, policies either embedded with existing policies either independent until 2025 [2].

Studies have indicated that nurses have negative attitudes [4,5,6] and low level of knowledge towards dementia care [7,8,9,10]. This fact leads to the assumption that those patients are in danger of care omissions. Nurses have a key role for the improvement of quality of care as they are the ones who have the most contact and time with the patients. The acquisition of a high level of knowledge and positive attitudes will upgrade nursing ethics especially compassion, cognitive and emotional empathy for PwD among nurses, resulting in the promotion of quality of care. A significant part of the WHO global plan is training health providers concerning the special needs and management of care for PwD. For the accomplishment of this target [2], WHO recommends the development of training programs for all health professional and the encouragement to adopt positive attitudes. Promoting understanding and training will help to reinforce health care and improve social results, mainly quality of life for PwD and their carers, even the wider society leading to better living experience and settings for those people.

PwD are more vulnerable to care than older people, as due to their cognitive impairment they cannot react or demand better quality of care. They are often marginalized and endangered from mistakes, omissions or even mistreatment, in relation with other groups of patients. This fact is attributed to the multidimensional nature, the memory and behavior problems, the comorbidities and the complexity of care as well as with the associated management problems. As a vulnerable group of people, PwD are in danger for abuse or neglect. The concept of "vulnerability" is defined as the reduced ability of an

individual or group to predict, cope, resist and recover from the effects of natural or man-made risks [11]. The concept is relative and dynamic in both directions.

During 2009, non-deliberate injury was the 7th cause associated with mistreatment of 65+ people [12,13]. According to the [14], the concept of "mistreatment" in the elderly is defined as *"the only or repetitive act, or the lack of appropriate action, arising in any relationship where there is the expectation of confidence harm or risk to the elderly person"*. Several studies have shown that the older people are at greater risk of neglect and the problem is more complicated by taking into account the level of co-morbidity and potential risk [15,16,17,18]. A study [19], has shown that chronic cases and the elderly, who had no apparent and immediate effects from the treatment, were often marginalized by health professionals. This focus on medical objectivity and impartiality is clearly rational and legitimate, but the consequences may be undesirable.

Highlighting the ethical perspective of missed nursing care it seems that this phenomenon undermines the violation of fundamental human rights. People over the age of 65 with cognitive decline are often overlooked of their lived experienced and the preservation of human rights [3]. In fact, people with "silent minds" are deprived of their liberty by denying civil and political rights to society or even during hospitalization. For PwD more emphasis is given on providing basic care and supervision rather than integrating them into the wider community, so the human rights of those individuals are marginalized [20]. In addition, the political controversy over the human rights of PwD focuses on the right to respect and dignity [21], ignoring the fundamental rights of freedom and decision-making [20].

In nursing the topic of missed care, although it has been proven to exist since 2009 [22a], is hardly acknowledged or discussed. The problem has recently brought up in the nursing scientific agenda through a European project[23] (http://www.cost.eu/COST_Actions/ca/CA15208) that aims to bring together scholars, practitioners and stakeholders to develop a responsive research agenda that identifies challenges and innovative cost-effective and patient-centered solutions associated with missed care. The project will also enable research and policy synergies by drawing out the implications of missed nursing care across countries and identify innovative delivery

models and strategies with an overall aim to address patient needs. This study is part of the project.

There are also some studies that brought evidence of care omissions and that nurses do not provide all the necessary care to patients [22a,b,24, 25]. The main reasons for that phenomenon were lack of resources and time, so nurses prioritize care, leading to some processes to be delayed [22a] or undone [26], or not completed[27, 28], or not delivered according to quality protocol standards [29]. It has been demonstrated that missed nursing care is an international and important phenomenon, which might take place more frequently, due to the fact that nurses are in continuous interactions with patients and they are called to response in the whole spectrum of patients' needs, in an extremely complex environment, taking multiple tasks at the same time. Although in the context of care impartiality is necessary, in exceptional circumstances a patient might be prioritized [30].

Two systematic reviews on missed nursing care [27, 31], have shown that communication, dental health, education, documentation, mobilization, supervision, update of care plan, personal care, the medication, preparation for discharge [27,32,33, 34,35,36, 37, 38], and psychological support [26] were the most frequent omissions by nurses. These studies have not indicated if missed nursing care was correlated with specific group of patients. A study [39] revealed that nurses prioritize care in the basis of age or mental impairment of the patient, resulting in discrimination of care for older people, as they come last, during prioritization process. Many studies have associated the quality of care and missed nursing care [19, 35, 40, 41, 42, 43]. In addition patient safety, falls, immobility, dyspnea, incontinence [22b, 41, 44, 45], pneumonia, urine infection, delirium [25, 26,46] and in hospital infections [26,41,45] have been proven as impact of the phenomenon on patients.

A systematic review [47] has identified the reasons for the low level of knowledge and negative attitudes and the beneficial action of intervention programs to nurses. The main objectives of the study are to reveal the level of knowledge and attitudes of nurses towards PwD and to detect if any nursing care is missed. Last objective, is the establishment of a qualified program, which will improve the quality of care, provided to PwD.

METHOD AND ANALYSIS

Aim

This study aims to advance the level of knowledge, promote positive attitudes of nurses and reduce care deficits towards PwD through the implementation of a training program. Specifically the aims are:

1. To explore the level of knowledge and nurses’ attitudes towards the care of PwD.
2. To explore the care and care deficits of PwD, aiming to get more information about nurses’ knowledge and attitudes, so as to strengthen the training program.
3. To implement a training program, in order to increase knowledge, improve attitudes and reduce missed care for patients with dementia

Design

This study is a mixed method study, consisting of three stages. Firstly, a descriptive study will take place, to evaluate the level of knowledge and attitudes of all acute hospital nurses, through the use of structured questionnaires. Secondly, an observation study will be held in order to detect the kind of care that is provided in hospital settings towards PwD. Lastly, a quasi-experimental study will follow with one group of nurses, including one pre and two posttests. This will be accomplished by the implementation of a one-day training program to two groups of acute hospital nurses. Each group will consist of 25 nurses and the intervention will be specifically designed for increasing the knowledge and attitudes of nurses towards PwD. The reasons that quasi-experimental design was selected are due to the fact that there will not be a control group, and the participants cannot be randomly selected because they will need to participate in their free time.

Stage 1 Evaluation of the level of knowledge and the attitudes of nurses towards dementia care.

Through a systematic review of the literature, regarding knowledge and attitudes of nurses towards dementia care it has been revealed that knowledge was lacking and attitudes were non-favorable [47]. So, there is a possibility that the quality of dementia care is affected. In this stage two structured questionnaires will be used: 1) the Dementia Knowledge Assessment Tool Version 2 [48] for knowledge and 2) the Dementia Attitudes Scale [49], as far as it concerns attitudes. Both instruments were used in previous studies supporting their validity and reliability [48, 49, 50, 51, 52]. The sample will include all nurses, working in acute hospital settings, specifically in medical, surgical and orthopedic departments, of the 5 main general hospitals of the country. The specific hospital departments were selected, due to the high accommodation frequency of PwD [21]. Power analysis revealed sample estimation at 364 participants. Approximately 400 questionnaires are planned to be distributed and the response rate must be over 70%. Pediatric wards, outpatient clinic, emergency and maternity department will be excluded as they do not provide care to those patients, as frequent as others wards. Inclusion criteria are:

- Registered nurses based on the National law
- Working in medical, surgical and orthopedic department of the hospital for at least one year
- Voluntary participation in study

Questionnaires will be completed anonymously and the aim of the study will be explained in the first page prior the questionnaires, along with the details for the contact person for further details. The completion of the questionnaires will be considered as the consent of participation. Questionnaires will be distributed by the researcher and returned to a closed box at the office of each ward in an envelope.

Dementia Knowledge Assessment Tool Version 2

The first part of both questionnaires will include demographic information. The Dementia Knowledge Assessment Tool Version 2 (DKAT) [48] is used to measure the knowledge of nurses and caregivers concerning dementia and was designed exclusively for these groups [49]. It contains 21 *correct / wrong /not know* answers for assessing knowledge regarding causes, risk factors, disease symptomatology, care, impact, evaluation and

management. The correct answers range from 0-21, with the highest score indicating more knowledge. It has been used by other researchers [48, 50] and it is a valid and reliable tool (Cronbach's alpha = 0.79) [48].

Dementia Attitude Scale

The Dementia Attitude Scale (DAS) [49] was designed to investigate nurses' attitudes towards PwD. It is divided into a seven-level Likert scale of 20 questions, which reflects the behavioral and cognitive components of nursing attitudes towards PwD [5]. It contains two factors (a) knowledge (b) attitudes with accepted reliability (Cronbach's alpha 0.83-0.85) [51] and validity ($r=0.96$) [49] in correlation with similar instruments [51]. Probable scores range from 20-140 with the highest score indicating more positive attitude [52]. Its development was based on the three-dimensional attitude model that defines three components: influence, behavior and knowledge [53]. It has been used in previous surveys [49, 51, 52] and is a commonly accepted and reliable measurement tool.

For the data analysis inferential analysis will be reported such as linear regression and parametric measures (t-test, ANOVA, confidence intervals and correlation coefficients Pearson) as needed and descriptive (mean, standard deviation, median, frequencies). Sociodemographic correlates will be assessed in correlation with the level of knowledge and attitudes. Considering data analysis for the Dementia Knowledge Assessment Tool version 2, descriptive statistic will be used and multiple regression analysis. This analysis will be followed to control confounder factors that might influence variables. For Dementia Attitude Scale, non-parametric test and test Wilcoxon will take place. All the analysis will be performed by SPSS 22.0. Multiple imputations will take place in order to handle missing data.

Both the questionnaires will be translated and back translated according to the guidelines suggested by WHO, 2016 [54] and the validation will include a test - re-test, Cronbach's alpha and a factor analysis. Translation process will include forward translation, then expert panel for backward translation, a pre-testing and cognitive interviewing, until we reach the final version. This procedure will be done during the pilot phase of the study that will include a sample of 100 nurses working in the emergency departments across the

country. Those 100 nurses will be included only for the pilot study and not for the main study. As nurses from the emergency department are not included in the main study, pilot study was selected to take place among this group of nurses. Furthermore, nurses working in emergency departments do not provide care to PwD that last more than one day, although PwD visit the particular department on frequent occasions. So, we concluded that it is interesting to investigate emergency department nurses' level of knowledge and attitudes, considering the frequent, but short term visit of PwD to the department. For the first attempt of this intervention we decided to include nurses from the general department since they have closer contact and care for longer periods patients with dementia. We are planning to include emergency department nurses at a later stage.

Stage 2 observation study to detect any missed nursing care towards PwD

Data from the observational study will be collected through field notes, in order to investigate care provided to PwD. Based on the hypothesis that if nurses' knowledge is low and their attitudes are negative, there is the possibility that care is not up to the expected quality standards. These data are expected to give more information as to the care of PwD and especially care deficits, care omissions and missed care, aiming to strengthen the training program and focus on specific issues that will facilitate the care delivered to this group of patients.

We have conducted a scoping review considering the methodology of observational study, so as to proceed with our design [55-61]. The observer will be the main researcher, which is a nurse. One week training and one week pilot study will precede the main study. Pilot study will include the determination and familiarization with the environment, the data collection process and co-ordination with the observation timetable [61]. This duration of time is expected to eliminate any factors that may influence nurses' behavior, due to observer presence. Reliability of the data, on stage 2, can be doubted, as nurse will not perform normal procedures with an observer in the room, but we expect that after 2 weeks of observer stay they will feel comfortable and continue their everyday routine. This is the reason that data from the first two weeks are not going to be analyzed.

The potential for nursing omissions towards PwD is a fairly sensitive issue that, if is explored through questionnaires, nurses may hide some information about what is actually done because of the fear of questioning their professionalism, so the observation method is expected to reflect a more objective picture of reality. Moreover, is the only method that can collect data from real settings and the validity and objectivity cannot be doubted, since the data are collected by an external observer. Field notes will not include any characteristic of patient or nurses.

a) Sample

The sample will include PwD, who are hospitalized for any reason. The sample strategy in observational studies is purposeful sampling, since the particular research topic is investigated in a pre-determined population. A patient will be observed for one shift daily (morning or evening). The night shift has been excluded, due to its uneven duration which is 12 hours compared to the 6-hours shift (morning-evening). The sample size will be determined by the data saturation criterion.

In qualitative methods, the sample is smaller and when the data renewal no longer exists, the collection process is considered adequate [62, 63]. Inclusion criteria will be the diagnosis of dementia [64-65] and the hospitalization of the person with dementia, regardless of the reasons. The researcher will be informed at the beginning of the shift by the departmental officer if PwD are hospitalized in the department. The researcher will ensure and manage confidentially the data and diagnosis and cannot use them for the purposes of any other research. In the case of more than one patient per ward, random sampling will be performed, and data will be collected for one patient at a time and then the patient will not be included again in the sample.

b) Duration of observation

The duration of the observational study will last 1 day per patient. If there is availability of patients the data collection process will last 10-12 days. In other case the process will last until we reach 10 patients, with the maximum duration one month [55, 58, 60,61,66,67].

(c) Wards

The departments that are going to be observed are Medical, Surgical and Orthopedic in one of the five selected hospitals. The specific sections of the hospital were selected on the basis of the Alzheimer's Society report [21], 2009, which showed that 14% of patients with dementia were admitted to hospital after falls, 12% for hip replacement, 9% for urinary tract infection, 7% for respiratory infection and 7% due to stroke. In addition, another study [68] added to the above mentioned reasons dehydration, as well.

The observer will stay in the patients' room, not wearing a nurse uniform, preserving at least 3 meters distance from the patients' bed [62, 69] and record everything she sees in the context of care in her field notes. This distance is probably predetermined for respect patient's privacy. The observer will not participate in any intervention or error in order not to influence the result of the study and the normal process of the department, with only exception if is a life or death issue. Additionally, no communication will take place with nurses, patients, or patients' relatives during the observers' stay. Each patient will be recorded in new field notes.

d) Field notes

Data collection in the observational study will be based on field notes written by the observer, during her stay in the patient's room. The notes will be "methodological", "descriptive" and "theoretical". Descriptive field notes will include information about anything the observer watches or hears, regarding communication among nurses-patient, process and environment characteristics [70, 71]. Methodological field notes will be comprised of the technique of data collection. In particular, those notes include the process that the observer will use to write down the data, for instance the adjustment of the observer in the culture of the organization [70]. Theoretical field notes regard the conscious, controlled efforts of the researcher to come to the essence of her notes. Those notes are the personal interpretation of data by the observer [71]. More specifically, the researcher tries to understand behaviors or processes and to document some ideas, questions, thoughts or concerns as a reflection of her data. Only the research team will be aware of the context of the field notes, so as not to influence the results of the study and

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to conserve the confidentiality and anonymity of the participants. Data will be coded and categorized, so content analysis will follow. As content analysis is a reflective process [72] the identification and condensation of the meaning units, the coding and the categorization into themes is going to be a repeated event, by at least two of the research team, in order to maintain the quality and the trustworthiness of the analysis [73]. Themes will emerge through the data and no software package will be used.

Stage 3 Quasi-experimental study

Once the descriptive and observation study have been completed, a quasi-experimental study, with a before and after design, which will include one group and one pre and two post tests will follow. This part of the study will include the organizing of a one day training course, which will facilitate nurses to provide a better and consistent care to PwD. The training will consist of various topics and will be conducted by dementia experts in order to describe, the pathophysiology of the disease and the appropriate care needed for these patients. The study has no costs, as the experts are willing to participate in the course free of charge. Furthermore, no economic outcomes are expected to emerge through the particular stage of the study.

The systematic review of the literature [47] considering intervention studies to nurses has detected eleven educational programs [5, 53, 74-82] with a large variety of designs. Most of them were seminars [75-82] lasting from 7 hours [75, 77], 1 day [79, 82], 3 days [76] to 15 weeks [81]. Other studies used one day workshops [74, 78], whilst another research team used a one day online seminar [51] or educational video [80]. This fact could be attributed to the deficiency of an established and validated program, so each research team created its own program for the purpose of each research.

For the purpose of the present study we have selected the “Getting to Know me” program (with the approval of the authors) [77], as it has checked validity and reliability but also it has been applied in more than one studies [77] and it has been adopted by the NHS. The creators suggest that the program can be applied to other countries, as well, as the results were beneficial for acute hospital nurses. However it is expected that after the observational study, some modifications will be necessary to be introduced in order to

focus on minimizing missed care. In particular, based on stage 1 and 2 results the program will be modified. For instance if the level of nurses' knowledge seems to be low on stage 1, emphasis is going to be given on the particular topic. Regarding stage 2 results if missed care is detected in specifics aspects of care eg. feeding, the training program will focus on that. In general as far as it concerns missed care, if this is proven through stage 2, a lecture focusing on this topic is going to be added in the training program.

a) Description of the program

This program is specifically designed for acute hospital nurses that provide care to PwD. It includes lectures, video, a guide for communication skills, the form "Getting to know me" and a 30 pages book. The main topics of lectures are introduction to dementia, holistic care, communication, impact of hospital environment, person centered-care and management of aggressive behavior. The program is going to be translated to Greek and some modifications will take place, so as to respond to study sample's needs and to the findings derived from the observation study. The modification will be an addition of an experiential workshop and participants will have more interaction through role play. The program will be implemented in two days and the sample will be twenty nurses per day, with a total number fifty nurses.

As the program includes many interaction exercises sample size was premeditated according to creators' suggestions about the number of participants, which is estimated to be 20 nurses per day [77]. Participant's number in those studies is also suggested by literature to be maximum 40 people, divided in smaller groups [5, 51, 77,79,81]. We concluded to include 25 nurses per day, so as to eliminate the risk of drops out. In addition, we have conducted a power analysis and the estimated sample size was calculated to include 20 participants. Response rate should be higher than 95% for the reliability and validity of the study. To achieve the response rate reminder phone calls to participants will take place after the duration of three months, by the PhD candidate.

Inclusion criteria will be the same as the descriptive stage of the study. However priority will be given to nurses who work most with PwD, such as medical, orthopedic or surgical

wards, since the descriptive study is going to take place among those departments. The setting of this phase is university's lecture hall and the target sample is 50 acute hospital nurses.

b) Evaluations

Three evaluations will include a) prior to the implementation of the program, b) immediately after the intervention c) the last one will take place three months after the intervention [75, 76, 82-85] in order to see if the effect of the program remains for a longer period. Data analysis will be the same as stage 1, since the tools that will be used on stage one and three are the same. The time intervals have been selected on the basis of international bibliography from interventional studies, which also studied the knowledge and attitudes of nurses in the care of dementia [8, 76, 82], or implemented other intervention programs in nurses [83-85].

Primary outcomes of this stage are 1) the evaluation of nurses' knowledge and attitudes which is expected to be advanced after the implementation of the program and 2) the reduction of nursing omissions during nursing care. Secondary outcomes is the upgrade of the quality of care provided to PwD, through the adoption of positive attitudes, 2) the reinforcement of sympathy among nurses to the particular group of patients and 3) the development of communication skills and management strategies on behalf of nurses, in order to reduce burden during nursing care of PwD.

Participants are going to be informed about the scope of the training program and their obligation to fill the three questionnaires before their registration to the training. The PhD candidate will be responsible for the information, registration and their consent to participate. The research team will be responsible for organizing, enrollment and coordinating the training course and the participation of nurses will be volunteering. If more than fifty nurses are willing to take part random sampling will be followed. A certification will be given after the completion of the last questionnaires to those who participate, in order to increase interest for joining the training course.

Data from the three stages are going to be storage in the researcher's office, where no one but the researcher is allowed entry. Data monitoring will be performed by the supervising

committee and the PhD candidate will be responsible for analyzing, coding and writing the data. Furthermore, the committee will conduct range checks of the values as far as it concerns the questionnaires. Regarding the observational data two members of the committee will separately proceed to the coding process and then a discussion will follow with the PhD candidate, in order to develop thematic analysis.

The translation process has been done during September-January 2019. The pilot study has started on 3rd of February and has ended on 29th of April 2019, so data from the pilot study have already been collected. The present stage of the study is on stage 1, the descriptive part. The questionnaires were distributed, since the 10th of May, 2019, and this phase is expected to be finalized until 15th-20th of June. The first results are expected on 1st of July 2019 from the descriptive stage and until 30th of September 2019 the qualitative findings will be available. Data from the third stage are expected between 10th-17th of February 2020, since the intervention is programmed to be implemented on 19th of September 2019 and the last data that are going to be collected are three months after the intervention. The timeline of the study is illustrated on Figure 1.

DISCUSSION

Nursing care rationing can be considered as the direct indicator of quality of care deficiencies, with a clear pathway for patient outcomes and their experiences. In addition, is a key concept for early detection of problems before major repercussions occur, making nurses and policy-makers to recognize where patients are at risk as soon as possible [86]. The vulnerable group of patients with cognitive impairment is the best example of complexity in the elderly, but with the highest rates of complications occurring during hospitalization. Omissions are not just a complete or a single unfortunate event, but a series of mild forms of neglect.

Nursing care rationing is an international phenomenon, as many studies investigated the kind of care which is missed [24, 25, 27, 32, 35-38, 45, 87], factors that influence the phenomenon [22a, 26, 40, 42, 43, 88, 89-92], the consequences on patients [19, 22b, 25-27, 40, 42, 43, 44, 46, 93, 94, 95] and on nurses [27, 42, 43, 96, 97, 98]. This study aims to add to the existing model of factors associated with nursing care rationing [29] the

factors of knowledge and attitudes, without marginalize the other factors already acknowledged (environmental, organizational, administrative). None of those studies have correlated nursing care rationing with a specific group of patients and since PwD constitute a major percentage of hospitalized patients, in correlation with the rapid epidemiological growth, the topic is of high importance. All in all, this is the first study that is going to recognize if there is any correlation among low level of knowledge and quality of care and implement an educational program, so as to promote care among PwD.

Although the reasons for care rationing have been investigated, this phenomenon is even observed in cases where the workload is not much. Nurses have become so familiar with the "chaos" associated with unexpected events and breaks in their processes, so they continue to act with prioritization even when they are not imposed by other factors [22a, 99]. There have been reports of doctors and nurses placing older people at a lower priority, with a lot of interventions and medications, but little care and comfort [19]. This event was described as spam, but it often happens. Prioritization seems to be implemented through traditional biomedical approaches that go beyond ethical issues [39].

Patient and Public Involvement

During the second stage of the study patients and their carer participation is of high importance, by consenting to being observed. If they are not willing to do so, the study design for stage two will not be achievable. Research questions were informed based on published literature regarding carers’ experience during hospitalization of PwD [21]. Also, informing them that care process is going to be observed they will share with us their priorities and their opinion about hospital care, so the outcome will be on stage three, as we will update our training program based on carers’ experience.

ETHICS AND DISSEMINATION

The protocol was approved by Cyprus National Bioethics committee (EEBK: 2018.01.02) and by the Research committee of the Ministry of Health. Access to the field of research was obtained by each hospital manager and the managers of each ward. The relatives of patients with dementia will be informed that patients will be observed and the aims of the study will be explained, so as to gain their permission.

After the observer will be informed about the rooms that hospice PwD, she will be responsible for the recruitment of the patients and their carers. She will explain to both of them the aim, the design and the volunteer nature of the study, along with contact details for all the research team. If they agree, the relative will be asked to sign on patients' behalf for participation in the study and then the data collection will start. Since PwD are characterized by cognitive impairment, their consent is often doubted. As patients' consent is an issue of conflict in the research field [100], we decided to proceed with the general practice regarding dementia studies and request relatives' signature [101], regardless of patients' capacity. The patient will be informed despite of his/her capacity, which is not going to be assessed. Also, they will be informed that study results will be available in lectures that the researchers make in cooperation with the national Alzheimer Society. In cases that are not able to participate they can contact a member of the research team and inform them about the results of the study

The anonymity, the trustworthiness and the process of the collected data will also be explained in the consent form both for the nurses and well as the relatives of PwD, that the data are going to be used only for the purpose of the particular study and when is finished are going to be destroyed. In order to remain the confidentiality and the anonymity of the participants none of the patients' or the nurses' identification will be included. Patients are going to be coded and no one except from the main researcher will be able to know to whom the data are referred. The research team will be the only one who will have access to the data. If any important modification of the protocol will take place all the relevant parties will be informed (Ethics Committee, Health Ministry). This study is in conjunction with the SPIRIT statement [102].

Dissemination strategy includes presentations in international and national scientific conferences. More emphasis will be given in nursing conferences, as the audience will be

more benefited in clinical practice. All the results are going to be submitted in peer-reviewed journals for publication. Moreover, the results of the intervention stage are going to be presented in policy makers in order for the program to be implemented in a broader population of nurses. The results of the study are going to inform future study, as well, targeting carers of PwD and evaluate if the usefulness is as important as to nurses.

Author statement

Authors' contributions: Melina Evripidou has written the manuscript. Evridiki Papastavrou as the main supervisor of the project, contributed and supervised the writing process, reviewed the manuscript and consulted the first author. Anastasios Merkouris and Andreas Charalambous have reviewed and contributed in writing the manuscript.

Funding: The research is supported by Leventis foundation grant number EPI009/181120/820750. Publication fees were granted by the Cyprus University of Technology Open Access Author Fund.

Competing interests: The authors declare that they have no competing interests.

Acknowledgements: The authors gratefully acknowledge nurses and departmental officers for their cooperation and the permission to conduct the observation study to their wards.

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References

1. Alzheimer's Association. Alzheimer's disease facts and figures. 2016. Available at: http://www.alz.org/documents_custom/2016-Facts-and-Figures-Fact-Sheet.pdf. Accessed 19 March 2019.
2. WHO. Dementia: a public health priority. 2012. Available at: http://www.who.int/mental_health/publications/dementia_report_2012/en/. Accessed 14 February 2019.
3. Knapp M. Economic outcomes and levers: impacts for individuals and society. *IntPsychogeriatr*. 2007;19(3):483-95.
4. Robinson A, Eccleston C, Annear M, Elliott K.E, Andrews S, Stirling C, Ashby M, Donohue C, Banks S, Toye C. &McInerney F. Who knows, who cares? Dementia knowledge among nurses, care workers, and family members of people living with dementia. *JournalofPalliativeCare*.2014; 30(3):158–165.
5. Bryans M, Keady J, Turner S, Wilcock J, Downs M &Iliffe S. An exploratory survey into primary care nurses and dementia care. *British Journal of Nursing*.2003;12(17):1029–1037.
6. Kada S, Nygaard H.A, Mukesh B.N &Geitung J.T. Staff attitudes towards institutionalized dementia residents. *Journal of Clinical Nursing*.2009;18(16): 2383–2392.
7. Josefsson K, Sonde L &Wahlin T.-B.R. Competence development of registered nurses in municipal elderly care in Sweden: a questionnaire survey. *International Journal of Nursing Studies*.2008;45(3):428–441.
8. Galvin J.E, Kuntemeier B, Al-Hammadi N, Germino J, Murphy-White M & McGillick J. “Dementia-friendly hospitals. *Alzheimer Disease & Associated Disorders*.2010;24(4):372–379.
9. Marx K.A, Stanley I.H, Van Haitsma K, Moody J, Alonzi D, Hansen B.R &Gitlin L.N. Knowing versus doing: Education and training needs of staff in a chronic care hospital unit for individuals with Dementia. *Journal of Gerontological Nursing*.2014;40(12):26–34.
10. Barrett J.J., Haley W.E., Harrell L.E. & Powers R.E. Knowledge about Alzheimer disease among primary care physicians, psychologists, nurses, and social workers. *Alzheimer Disease & Associated Disorders*.1997;11(2):99–106.

11. International Federation of Red Cross and Red Crescent Societies (IFRC). What is vulnerability?. 2014. <http://www.ifrc.org/en/what-we-do/disaster-management/about-disasters/what-is-a-disaster/what-is-vulnerability/>. Accessed 21st January 2019.

12. Centers for Disease Control and Prevention (CDC). Elder Abuse. 2017. <https://www.cdc.gov/violenceprevention/elderabuse/index.html>. Accessed 3rd January 2019.

13. Centers for Disease Control and Prevention (CDC). Elder Abuse. 2017. <https://www.cdc.gov/violenceprevention/elderabuse/index.html>. Accessed 3rd January 2019.

14. WHO. Management of substance abuse. Process of translation and adaption of instruments.2016. http://www.who.int/substance_abuse/research_tools/translation/en/. Accessed 13th March 2019.

15. Dixon J, Manthorpe J, Biggs S, Mowlam A, Tennant R., Tinker A&McCreadie C. Defining elder mistreatment: Reflections on the United Kingdom study of abuse and neglect of older people. *Ageing & Society*.2010;30(3)403–420.

16. Gilhooly M.L.M, Cairns D, Davies M, Harries P, Gilhooly K.J, Notley E. Framing the detection of financial elder abuse as bystander intervention: Decision cues, pathways to detection and barriers to action. *Journal of Adult Protection*.2013;15(2):54–68.

17. Manthorpe J. Elder abuse. In: Denning. Oxford textbook of old age psychiatry (2nd ed.), Oxford: Oxford University Press. 2013. p.779-83.

18. Manthorpe J. The abuse, neglect and mistreatment of older people with dementia in care home and hospitals in England: the potential for secondary data analysis: innovative practice. *Dementia*.2015;14(2):273-9.

19. Skirbekk H. & Nortvedt P. Making a difference: A qualitative study on care and priority setting in health care. *Health Care Analysis*.2011;19(1):77–88.

20. Boyle M, Williams B, Tedd B, Molloy A.et al. Attitudes of undergraduate health science students towards patients with intellectual disability, substance abuse, and acute mental illness: a cross-sectional study. *BMC Medical Education*. 2010.

- <https://bmcmmededuc.biomedcentral.com/articles/10.1186/1472-6920-10-71>.
Assessed 22th February 2019.
21. Alzheimer Society. Counting the cost. 2009.
https://www.alzheimers.org.uk/download/downloads/id/787/counting_the_cost.pdf.
f. Accessed 9th February 2019.
 22. a) Kalisch B.J, Landstrom G.L. & Hinshaw A.S. Missed nursing care: A concept analysis. *Journal of Advanced Nursing*.2009;65(7):1509–1517.
b) Kalisch B,Tschannen D, Lee H, FrieeseC. Hospital variation in missed nursing care. *Am J Med Qual*.2012;26(4):291–299.
 23. Scott P. A, Harvey C, Felzmann H, Suhonen R, Habermann M, Halvorsen K, Papastavrou E. Resource allocation and rationing in nursing care: A discussion paper. *Nursing Ethics*.2018; <https://doi.org/10.1177/0969733018759831>
 24. Papastavrou E. The ethics of care rationing within the current socioeconomic constraints. *Health Science Journal*.2012;6(3):362–364.
 25. Ball J, Griffiths P, Rafferty A.M., Lindqvist R, Murrels T. QUANTITATIVE A cross-sectional study of ‘care left undone’ on nursing shifts in hospitals. *J of AdvNurs*. 2016;72(9):2086-97.
 26. Schubert M, Carke S, Glass T, Schaffert-Witvliet B, De Geest S. Identifying thresholdsfor relationship between impacts of rationing of nursing care and nurse and patient reported Outcomes in Swiss hospitals : A correlational study.*Int J nurs Stud*.2010; 46(7):884–893.
 27. Papastavrou E, Andreou P, Efstathiou G. Rationing of nursing care and nurses-patient outcomes: a systematic review of quantitative studies. *Int J Health Manage*.2014;2(1):3-25.
 28. Verall C, Aberly E, Harvey C, Henderson J, Willis E, Hamilton P, Toffoli L, Blackmann I. Nurses and midwives perceptions of missed nursing care--A South Australian study.*Collegian*.2015;22(4).413-20.
 29. Blackman I. Factors influencing why nursing care is missed. *Journal of Clinical Nursing*.2015;24(1–2):47–56.
 30. Nortvedt P, Hem M.H. & Skirbekk H. The ethics of care: Role obligations and moderate partiality in health care. *Nursing ethics*.2011;18(2):192–200.

31. Jones T, Hamilton P, Murry N. Unfinished nursing care, missed care and implicitly rationed care: state of the science review. *Int J of Nursing Studies*.2015;52(6): 1121-37.

32. Kalisch BJ, Xie B, Dabney BW. Patient-reported missed nursing care correlated with adverse events. *Am J Med Qual*.2014;29:415–22.

33. Kalisch BJ, Tschannen D, Lee KH. Missed nursing care, staffing, and patient falls. *J NursCare Qual*.2012;27:6–12

34. Lucero R. Nursing Informatics Implications from a Study of Unmet Nursing Care Needs. *Connecting Health and Humans*.2009;5043:817–821.

35. Aiken LH, Sloane D, Griffiths P For the RN4CAST Consortium, et al. Nursing skill mix in European hospitals: cross-sectional study of the association with mortality, patient ratings, and quality of care. *BMJ Qual Saf*.2017;26:559-568.

36. Morin D, Leblanc N. Less money, less care: how nurses in long-term care allocate hours of needed care in a context of chronic shortage. *Int J Nurs Pract*.2005; 11(5):214–220.

37. Kalisch B.J, Xie B. Errors of omission: missed nursing care. *Western J. Nurs. Res*.2014;36(7): 875–890.

38. Knopp-Sihota JA, Niehaus L, Squires JE, Norton PG, Estabrooks CA. Factors associated with rushed and missed resident care in western Canada nursing homes: a cross-sectional survey of health care aides. *J Clin Nurs*.2015;24:1815-25.

39. Pedersen R, Nortvedt P, Nordhaug M, Slettebo A, Grothe KH et al. In quest of justice? Clinical prioritisation in healthcare for the aged. *Journal of medical ethics*.2008;34(4):230–5.

40. Schubert M, Glass TR, Clarke SP, Schaffert-Witvliet B, De Geest S. Validation of the basel extent of rationing of nursing care instrument. *Nurs Res*.2007;55(6):416–424.

41. Sochalski J. Is more better?: the relationship between nurse staffing and the quality of nursing care in hospitals. *Med Care*.2004;42(2):II-67–II-73.

42. Ausserhofer D, Schubert M, Desmedt M, Blegen M.A., De Geest S., Schwendimann R. The association of patient safety climate and nurse-related organizational factors with selected patient outcomes: a cross-sectional survey.

- Int. J. Nurs. Stud.*2013;50(2):240–252.
43. Ausserhofer D, Zander B, Busse R, Schubert M, De Geest S, Rafferty A.M, et al. Prevalence, patterns and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. *Br. Med. J. Qual. Safety*.2014;23(2):126– 135.
44. Lucero R.J, Lake E.T, Aiken L.H. Nursing care quality and adverse events in US hospitals. *J. Clin. Nurs.*2010;19(15–16):2185–2195.
45. Hayward R.A, Asch S.M, Hogan M.M, Hofer T.P, Kerr E.A. Sins of omission: getting too little medical care may be the greatest threat to patient safety.*J.Gen. Intern. Med.*2005;20:686–691.
46. Brown P, Fraser K, Wong CA, Muise M, Cummings G. Factors influencing intentions to stay and retention of nurse managers: a systematic review. *J NursManag*.2012; DOI: 10.1111/j.1365-2834.2012.01352.x
47. Evripidou M, Charalambous A, Middleton N, Papastavrou E. Nurses' knowledge and attitudes about dementia care: systematic literature review. *PerspectivPsychiatr Care* 2018.Doi: 10.1111/ppc.12291.
48. Toye C, Lester L, Popescu A, McInerney F, Andrews S, Robinson AL. Dementia Knowledge Assessment Tool Version Two: development of a tool to inform preparation for care planning and delivery in families and care staff.*Dementia* (London).2014;13(2):248-56.
49. O'Connor M, McFadden S. Development and Psychometric Validation of Dementia Attitude Scale. *Int J of Alzheimer Disease*.2010.doi: 10.4061/2010/454218.
50. Robinson A, Eccleston C, Annear M, Elliott K.E, Andrews S, Stirling C, Ashby M, Donohue C, Banks S, Toye C. &McInerney F. Who knows, who cares? Dementia knowledge among nurses, care workers, and family members of people living with dementia. *Journal of Palliative Care*.2014;30(3):158–165.
51. Kimzey M, Matel-Smith B, Alfred D. The impact of educational experiences on nursing students' knowledge and attitudes toward people with Alzheimer's disease: A mixed method study. *Nurse Education Today*.2016;46:57-63.
52. Scerri A, Scerri C. Nursing students' knowledge and attitudes towards dementia-

- a questionnaire survey. *Nurse Education Today*.2012;33(9):962-8.
53. Breckler S.J. “Empirical validation of affect, behavior, and cognition as distinct components of attitude”. *Journal of Personality and Social Psychology*.1984; 47(6):1191–1205.
54. WHO. Management of substance abuse. Process of translation and adaption of instruments.2016.
http://www.who.int/substance_abuse/research_tools/translation/en/.Accessed 13th September 2018.
55. Välimäki T, Vehviläinen-Julkunen K, Pietilä AM. Diaries as research data in a study on family caregivers of people with Alzheimer's disease: methodological issues. *J AdvNurs*.2007;59(1):68-76.
56. Ballermann MA, Shaw NT, Mayes DC, Gibney RT, Westbrook JI. Validation of the Work Observation Method By Activity Timing (WOMBAT) method of conducting time-motion observations in critical care settings: an observational study. *BMC Med Inform Decis Mak*.2011;17:11:32.
57. Jackson D, Wilkes L, Luck L. Cues that predict violence in the hospital setting: findings from an observational study.*Collegian*.2014;21(1):65-70.
58. D’Antonio S, Bagnasco A, Bonetti L, Sasso L. Observation study on interruptions during nurses work in two surgical wards of a hospital in Liguria. *Prof Infirm*.2014;67(4):211-8.
59. Clisset P, Porock D, Harwood RH, Gladman JR. The response of healthcare professionals to the admission of people with cognitive impairment to acute hospital setting: an observation and interview study. *J Clin Nurs*.2014;23(13-14):1820-9.
60. Hoviattalab K, HashemizadehH,Cruz G, Halfens Ruud J G, Dassen T. Nursing practice in the prevention of pressure ulcers : An observational study of German Hospitals Nursing practice in the prevention of pressure ulcers : an observational study of German Hospitals. *J Clin Nurs*.2015;11-12:1513-24.
61. Tan Y, Wai T, Sim C,I Ng. Optimising peripheral venous catheter usage in the general inpatient ward : a prospective observational study.*JClin Nurs*.2016;26:133-39.

62. Cohen L, Manion L, & Morrison K. Research methods in education. London, Routledge.2007.
63. Marshall M. Sampling for qualitative research. *Family Practice*.1996;13(6):5225.
64. Streit S, Limacher A, Zeller A, Burrge M. D. Detecting dementia in patients with normal neuropsychological screening by Short Smell Test and Palmo-Mental Reflex Test: an observational study. *BMC Geriatrics*.2015;15:90.
65. Travers C, Byrne G.J, Pachana NA, Klein K, Gray LC. Prospective observational study of dementia in older patients admitted to acute hospitals. *Australas J Ageing*.2014;33(1):55-8.
66. Hager K, Calabrese P, Frolich L, Gobel C, Berer FM. An observational clinical study of the efficacy and tolerability of donepezil in the treatment of Alzheimer's disease. *Dement GeriatrCogn Disord*.2003;15(4):189-98.
67. Goudra B, Singh P.M,Galvin E. Comparison of Compliance of Glove Use Among Anesthesia Providers: A Prospective Blinded Observational Study. *AANA Journal*.2014; 82(5):363-67.
68. Natalwala A, Potluri R, Uppal H, Heun R. Reasons for hospital admissions in dementia patients in Birmingham, UK, during 2002-2007.*Dementia GeriatrCogn Disord*.2008;26(6):499-505.
69. Creswell J, Vicki L, Plano C. Designing and conducting mixed method research. Los Angeles: SAGE Publications. 2011.
70. Bernard H.R. Research methods in anthropology: Qualitative and quantitative approaches. Lanham, MD: AltaMira Press.2011.
71. Lonner W.G, Berry J.W. Field notes in cross-cultural research. Newbury Park.CA: Sage Publications. 1986.
72. Erlingsson G, Brysiewicz P. A hands-on guide to doing content analysis. *African Journal of Emergency Medicine*.2017;7(3):93-99.
73. Bengtsson M. How to plan and perform a qualitative study using content analysis. *Nursing plan open*.2016;2:8-14.
74. Kang Y, Moyle W, Venturato L. Korean nurses' attitudes towards older people with dementia in acute care settings. *International Journal of Older People Nursing*.2011;6(2):143-152.

75. Galvin J.E, Kuntemeier B, Al-Hammadi N, Germino J, Murphy-White M. &McGillick J. “Dementia-friendly hospitals. *Alzheimer Disease & Associated Disorders*.2010;24(4):372–379.

76. Surr C.A, Smith S.J, Crossland J. & Robins J. Impact of a person-centred dementia care training programme on hospital staff attitudes, role efficacy and perceptions of caring for people with dementia: a repeated measures study. *International Journal of Nursing Studies*.2015;53:144–151.

77. Elvish R, Burrow S, Cawley R, Harney K, Graham P, Pilling M, Gregory J, Roach P, Fossey J. & Keady J. ‘Getting to know me’: the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & Mental Health*.2014;18(4):481–488.

78. Manthorpe J, Iliffe S. & Eden A. Early recognition of dementia by nurses. *Journal of Advanced Nursing*.2003;44(2):183–191.

79. Davison T.E, McCabe M.P, Visser S, Hudgson C, Buchanan G. & George K. Controlled trial of dementia training with a peer support group for aged care staff. *International Journal of Geriatric Psychiatry*.2007;22(9):868–873.

80. EinangAlnes R, Kirkevold M. &Skovdahl K. Insights gained through MarteMeo counselling: experiences of nurses in dementia specific care units. *International Journal of Older People Nursing*.2011;6(2):123–132.

81. McCaffrey R, Tappen R.M, Lichtstein D.M. &Friedland M. Interprofessional education in community-based Alzheimer’s disease diagnosis and treatment. *Journal of Interprofessional Care*.2013;27(6):1356–1820.

82. Palmer J.L, Lach H.W, McGillick J, Murphy-White M, Carroll M.B. & Armstrong J.L. The dementia friendly hospital initiative education program for acute care nurses and staff. *The Journal of Continuing Education in Nursing*.2014;45(9):416–424.

83. Gustafsson M, Bohman DM, Borglin G. Challenges of conducting experimental studies within a clinical nursing context. *ApplNurs Res*.2014;27(2):133-6.

84. Borglin G, Gustafsson M, Krona H. A theory-based educational intervention targeting nurses' attitudes and knowledge concerning cancer-related pain

- management: a study protocol of a quasi-experimental design. *BMC Health Serv Res.*2011;23(11):233.
85. Mahedran R, Tan J, Griva K, Lim H, Ng H.Y, Chua J, Lim, SE and Kua EH. A pilot, quasi-experimental, mixed methods investigation into the efficacy of a group psychotherapy intervention for caregivers of outpatients with cancer: the COPE study protocol. *BMJ Open.*2015; 5(11):e008527.
86. Bail K, Berry H, Grealish L, Draper B, Karmel R, Gibson D. & Peut A. Potentially preventable complications of urinary tract infections, pressure areas, pneumonia, and delirium in hospitalised dementia patients: Retrospective cohort study. *BMJ Open.*2013;3:6.
87. Papastavrou E, Charalambous A, Vryonides S, Eleftheriou C, Merkouris A. To what extent are patients' needs met on oncology units? The phenomenon of carer rationing. *Eur J Oncol Nurs.*2016;21:48-56.
88. Chassin M.R, Galvin R.W. The National Roundtable on Health Care Quality. The urgent need to improve health care quality: Institute of Medicine National Roundtable on Health Care Quality. *J. Am. Med. Assoc.*1998;280(11):1000–1005
89. El-Jardali F, Lagace' M. Making hospital care safer and better: the structure–process connection leading to adverse events. *Healthc. Q.*2005;8(2):40–48
90. Halvorsen K, Slettebø A, Nortvedt P, Pedersen R, Kirkevold M, Nordhaug M, Brinchmann BS. Priority dilemmas in dialysis – The impact of old age Priority dilemmas in dialysis : the impact of old age. *J Med ethics.*2008;34(8):585-9.
91. Tschannen D, Kalisch BJ, Lee KH. Missed nursing care: the impact on intention to leave and turnover. *Can J Nurs Res.*2010;42(4):22–39
92. Castner J, Wu Y.W.B, Dean-Baar S. Multi-level model of missed nursing care in the context of hospital merger. *Western J. Nurs.Res.*2014.
<http://dx.doi.org/10.1177/0193945914535670> Accessed 11th January 2019.
93. Williams J. Care quality Commission Dignity and nutrition inspection program: National overview.2011.https://www.cqc.org.uk/sites/default/files/documents/20111007_di

gnity_and_nutrition_inspection_report_final_update.pdf Accessed 1st October 2018.

94. McWhirter JP, Pennington CR. Incidence and recognition of malnutrition in hospital. *BMJ*.1994;308(6934):945-8.

95. Rochefort CM, Clarke S. Nurses’ work environments, care rationing, job outcomes, and quality of care on neonatal units. *J Adv Nurs*.2010;66(10):2213–2224.

96. Dhaini SR, Zúñiga F, Ausserhofer D, Simon M, Kunz R, De Geest S, Schwendimann R. Care workers health in Swiss nursing homes and its association with psychosocial work environment: A cross-sectional study. *Int J Nurs Stud*.2016;53:105-15.

97. Vryonides S, Papastavrou E. & Charalambous A. The ethical dimension of nursing care rationing : A thematic synthesis of qualitative studies. *Nursing Ethics*.2015;22(311):881–900.

98. Vryonides S, Papastavrou E, Charalambous A, Andreou P, Eleftheriou C, Merkouris A. Ethical climate and missed nursing care in cancer care units. *Nurs Ethics*.2016;27.pii:0969733016664979.

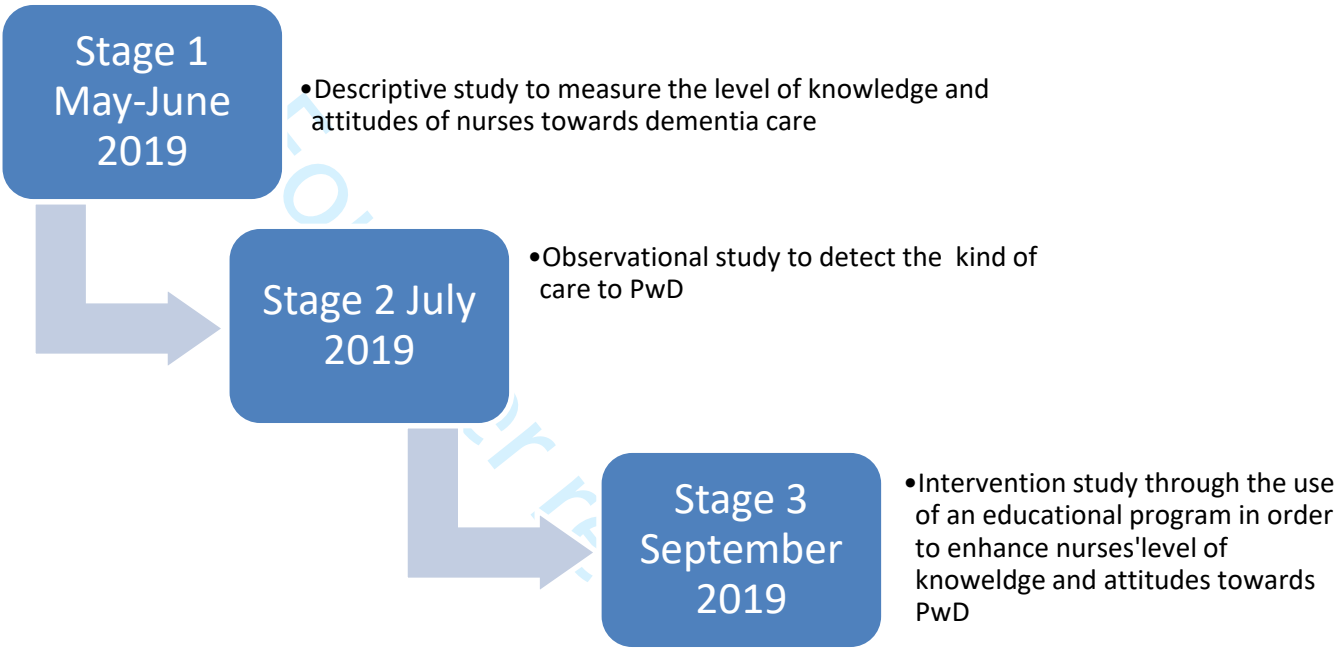
99. Kalisch BJ. Missed nursing care: a qualitative study. *J Nurs Care Qual*.2006;21(4):306–313.

100. Howe E. Informed Consent, participation in research and the Alzheimer patient. *Innov Clin Neurosci*. 2012;9:47-51.

101. Hedge S, Ellajisyula R. Capacity issues and decision-making in dementia. *Ann Indian Acad Neurol*. 2016;19:34-39.

102. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *AnnIntern Med*.2013;158:200-207.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Check
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	35
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 35
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	8

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	N/A
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	17-18
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	18
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	17
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	19
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14, 17

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	18
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	18
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	18
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	18
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11,15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18-19

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18-19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	21
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14,16,20,21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	35
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	35
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	11, 20
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

BMJ Open

Implementation of a training program to increase knowledge, improve attitudes and reduce nursing care omissions towards patients with dementia in hospital settings: a mixed method study protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030459.R2
Article Type:	Protocol
Date Submitted by the Author:	16-Jun-2019
Complete List of Authors:	Evripidou, Melina; Cyprus University of Technology, Nursing Merkouris, Anastasios; Cyprus University of Technology Faculty of Health Sciences, Nursing, School of Health Sciences Charalambous, Andreas; Cyprus University of Technology; Turun Yliopisto, Nursing Papastavrou, Evridiki; Cyprus University of Technology, nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Ethics, Nursing
Keywords:	Rationing < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL ETHICS, MEDICAL EDUCATION & TRAINING, Dementia < NEUROLOGY

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Implementation of a training program to increase knowledge, improve attitudes and reduce nursing care omissions towards patients with dementia in hospital settings: a mixed method study protocol.

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Keywords: *nurses, dementia, knowledge, attitudes, care*

Word counts: 5847

ABSTRACT

Introduction: There is evidence showing that when nurses have to allocate their time because of a lack of resources, older patients and especially those with dementia have a secondary care priority. The purpose of this study is to advance the level of knowledge, promote positive attitudes of nurses and reduce care deficits towards PwD through the implementation of a training program. The program will be enriched by an observational study of the care of patients with dementia to identify areas of missed care.

Method and analysis: This study will follow a mixed methodology consisting of three stages; 1) evaluation of the level of nurses' knowledge and attitudes towards dementia care through the use of structured questionnaires, 2) observational study to evaluate nursing care in hospital settings, in order to detect any missed care, 3) quasi-experimental study, with a before and after design, through the implementation of the training program in order to increase nurses' knowledge, improve attitudes and consequently to promote care for patients with dementia. The data will be analyzed with descriptive and inferential statistics with the use of the SPSS 24.0 and with content analysis as regards to the observational data.

Ethics and dissemination: The protocol was approved by the National Bioethics committee and other local committees (EEBK: 2018.01.02). The participants will give their informed consent and the anonymity and confidentiality. Also, the protection of data will be respected. The results of the study will be disseminated in peer-reviewed international journals and conferences. If the intervention is successful, the training package will be given to the Continuous education unit of the National Professional Association in order to be used on a regular basis.

Article summary

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Strengths of the study

- The main strength of the study lies in the fact that missed care that is mainly measured through self-reporting instruments, will be detected through observation, increasing the innovation of the methodological approach of the problem.
- The educational intervention will not only focus on dementia knowledge deficiency, but it will also address specific areas of missed care for patients with dementia.

Limitations of the study

- The intervention will last for only one day and it is not certain that the effects will last for a long time, meaning that there will be a need to repeat educational interventions at a later stage.
- The study is going to be conducted only in three wards of the hospital, although nursing care settings are differential in other wards.
- During the second phase of the study the total number of nurses per ward may be affected by sick leaves or training leaves and this might influence normal nursing care procedures.

INTRODUCTION

People with dementia (PwD) occupy 25% of hospital beds [1] and this number is expected to triple by 2050, considering the rapid epidemiological increment of the disease [2]. This group of patients is characterized by cognitive impairment placing them in an unfavorable position to demand the best possible care like other patients [3]. Consequently they might be in great danger of neglect. The increase in life expectancy associated with the multidimensional problem of dementia, inevitably leads to the need to investigate this topic. WHO 2017 [2], has highlighted the importance of the problem about dementia care in a global action plan on the public health response to dementia and set as a target 75% of countries to develop national policies, plans, policies either embedded with existing policies either independent until 2025 [2].

Studies have indicated that nurses have negative attitudes [4-6] and low level of knowledge towards dementia care [7-10]. This fact leads to the assumption that those patients are in danger of care omissions. Nurses have a key role for the improvement of quality of care as they are the ones who have the most contact and time with the patients. The acquisition of a high level of knowledge and positive attitudes will upgrade nursing ethics especially compassion, cognitive and emotional empathy for PwD among nurses, resulting in the promotion of quality of care. A significant part of the WHO global plan is training health providers concerning the special needs and management of care for PwD. For the accomplishment of this target [2], WHO recommends the development of training programs for all health professional and the encouragement to adopt positive attitudes. Promoting understanding and training will help to reinforce health care and improve social results, mainly quality of life for PwD and their carers, even the wider society leading to better living experience and settings for those people.

PwD are more vulnerable to care omissions than older people, as due to their cognitive impairment they cannot react or demand better quality of care. They are often marginalized and endangered from mistakes, omissions or even mistreatment, in relation with other groups of patients. This fact is attributed to the multidimensional nature, the memory and behavior problems, the comorbidities and the complexity of care as well as with the associated management problems. As a vulnerable group of people, PwD are in

danger for abuse or neglect. The concept of "vulnerability" is defined as the reduced ability of an individual or group to predict, cope, resist and recover from the effects of natural or man-made risks [11]. The concept is relative and dynamic in both directions.

During 2009, non-deliberate injury was the 7th cause associated with mistreatment of 65+ people [12,13]. According to the [14], the concept of "mistreatment" in the elderly is defined as *"the only or repetitive act, or the lack of appropriate action, arising in any relationship where there is the expectation of confidence harm or risk to the elderly person"*. Several studies have shown that the older people are at greater risk of neglect and the problem is more complicated by taking into account the level of co-morbidity and potential risk [15-18]. A study [19], has shown that chronic cases and the elderly, who had no apparent and immediate effects from the treatment, were often marginalized by health professionals. This focus on medical objectivity and impartiality is clearly rational and legitimate, but the consequences may be undesirable.

Highlighting the ethical perspective of missed nursing care it seems that this phenomenon undermines the violation of fundamental human rights. People over the age of 65 with cognitive decline are often overlooked in their lived experienced and the preservation of human rights [3]. In fact, people with "silent minds" are deprived of their liberty by denying civil and political rights to society or even during hospitalization. For PwD more emphasis is given on providing basic care and supervision rather than integrating them into the wider community, so the human rights of those individuals are marginalized [20]. In addition, the political controversy over the human rights of PwD focuses on the right to respect and dignity [21], ignoring the fundamental rights of freedom and decision-making [20].

In nursing the topic of missed care, although it has been proven to exist since 2009 [22,23], is hardly acknowledged or discussed. The problem has recently brought up in the nursing scientific agenda through a European project[24] (http://www.cost.eu/COST_Actions/ca/CA15208) that aims to bring together scholars, practitioners and stakeholders to develop a responsive research agenda that identifies challenges and innovative cost-effective and patient-centered solutions associated with missed care. The project will also enable research and policy synergies by drawing out

the implications of missed nursing care across countries and identify innovative delivery models and strategies with an overall aim to address patient needs. This study is part of the project.

There are also some studies that brought evidence of care omissions and that nurses do not provide all the necessary care to patients [22-26]. The main reasons for that phenomenon were lack of resources and time, so nurses prioritize care, leading to some processes to be delayed [22] or undone [27], or not completed [28, 29], or not delivered according to quality protocol standards [30]. It has been demonstrated that missed nursing care is an international and important phenomenon, which might take place more frequently, due to the fact that nurses are in continuous interactions with patients and they are called to response in the whole spectrum of patients' needs, in an extremely complex environment, taking multiple tasks at the same time. Although in the context of care impartiality is necessary, in exceptional circumstances a patient might be prioritized [31].

Two systematic reviews on missed nursing care [28, 32], have shown that communication, dental health, education, documentation, mobilization, supervision, update of care plan, personal care, the medication, preparation for discharge [28,33-39], and psychological support [27] were the most frequent omissions by nurses. These studies have not indicated if missed nursing care was correlated with a specific group of patients. A study [40] revealed that nurses prioritize care in the basis of age or mental impairment of the patient, resulting in discrimination of care for older people, as they come last, during prioritization process. Many studies have associated the quality of care and missed nursing care [19, 36, 41-44]. In addition patient safety, falls, immobility, dyspnea, incontinence [23, 42, 45, 46], pneumonia, urine infection, delirium [26, 27,47] and in hospital infections [27,42,46] have been proven as an impact of the phenomenon on patients.

A systematic review [48] has identified the reasons for the low level of knowledge and negative attitudes and the beneficial action of intervention programs to nurses. The main objectives of the study are to reveal the level of knowledge and attitudes of nurses towards PwD and to detect if any nursing care is missed. Last objective, is the

establishment of a qualified program, which will improve the quality of care, provided to PwD.

METHOD AND ANALYSIS

Aim

This study aims to advance the level of knowledge, promote positive attitudes of nurses and reduce care deficits towards PwD through the implementation of a training program. Specifically the aims are:

- 1. To explore the level of knowledge and nurses’ attitudes towards the care of PwD.
- 2. To explore the care and care deficits of PwD, aiming to get more information about nurses’ knowledge and attitudes, so as to strengthen the training program.
- 3. To implement a training program, in order to increase knowledge, improve attitudes and reduce missed care for patients with dementia

Design

This study is a mixed method study, consisting of three stages. Firstly, a descriptive study will take place, to evaluate the level of knowledge and attitudes of all acute hospital nurses, through the use of structured questionnaires. Secondly, an observation study will be held in order to detect the kind of care that is provided in hospital settings towards PwD. Lastly, a quasi-experimental study will follow with one group of nurses, including one pre and two posttests. This will be accomplished by the implementation of a one-day training program to two groups of acute hospital nurses. Each group will consist of 25 nurses and the intervention will be specifically designed for increasing the knowledge and attitudes of nurses towards PwD. The reasons that quasi-experimental design was selected are due to the fact that there will not be a control group, and the participants cannot be randomly selected because they will need to participate in their free time.

Stage 1 Evaluation of the level of knowledge and the attitudes of nurses towards dementia care.

Through a systematic review of the literature, regarding knowledge and attitudes of nurses towards dementia care it has been revealed that knowledge was lacking and attitudes were non-favorable [48]. So, there is a possibility that the quality of dementia care is affected. In this stage two structured questionnaires will be used: 1) the Dementia Knowledge Assessment Tool Version 2 [49] for knowledge and 2) the Dementia Attitudes Scale [50], as far as it concerns attitudes. Both instruments were used in previous studies supporting their validity and reliability [49, 50, 51-53]. The sample will include all nurses, working in acute hospital settings, specifically in medical, surgical and orthopedic departments, of the 5 main general hospitals of the country. The specific hospital departments were selected, due to the high accommodation frequency of PwD [21]. Power analysis revealed sample estimation at 364 participants. Approximately 400 questionnaires are planned to be distributed and the response rate must be over 70%. Pediatric wards, outpatient clinic, emergency and maternity department will be excluded as they do not provide care to those patients, as frequently as others wards. Inclusion criteria are:

- Registered nurses based on the National law
- Working in medical, surgical and orthopedic department of the hospital for at least one year
- Voluntary participation in study

Questionnaires will be completed anonymously and the aim of the study will be explained in the first page prior to the questionnaires, along with the details for the contact person for further details. The completion of the questionnaires will be considered as the consent of participation. Questionnaires will be distributed by the researcher and returned to a closed box at the office of each ward in an envelope.

Dementia Knowledge Assessment Tool Version 2

The first part of both questionnaires will include demographic information. The Dementia Knowledge Assessment Tool Version 2 (DKAT) [49] is used to measure the knowledge

of nurses and caregivers concerning dementia and was designed exclusively for these groups [51]. It contains 21 *correct / wrong /not know* answers for assessing knowledge regarding causes, risk factors, disease symptomatology, care, impact, evaluation and management. The correct answers range from 0-21, with the highest score indicating more knowledge. It has been used by other researchers [49, 51] and it is a valid and reliable tool (Cronbach's alpha = 0.79) [49].

Dementia Attitude Scale

The Dementia Attitude Scale (DAS) [50] was designed to investigate nurses' attitudes towards PwD. It is divided into a seven-level Likert scale of 20 questions, which reflects the behavioral and cognitive components of nursing attitudes towards PwD [5]. It contains two factors (a) knowledge (b) attitudes with accepted reliability (Cronbach's alpha 0.83-0.85) and validity ($r=0,96$) [50] in correlation with similar instruments [52]. Probable scores range from 20-140 with the highest score indicating more positive attitude [53]. Its development was based on the three-dimensional attitude model that defines three components: influence, behavior and knowledge [54]. It has been used in previous surveys [50, 52, 53] and is a commonly accepted and reliable measurement tool.

For the data analysis inferential analysis will be reported such as linear regression and parametric measures (t-test, ANOVA, confidence intervals and correlation coefficients Pearson) as needed and descriptive (mean, standard deviation, median, frequencies). Sociodemographic correlates will be assessed in correlation with the level of knowledge and attitudes. Considering data analysis for the Dementia Knowledge Assessment Tool version 2, descriptive statistic will be used and multiple regression analysis. This analysis will be followed to control confounder factors that might influence variables. For Dementia Attitude Scale, non-parametric test and test Wilcoxon will take place. All the analysis will be performed by SPSS 22.0. Multiple imputations will take place in order to handle missing data.

Both the questionnaires will be translated and back translated according to the guidelines suggested by WHO, 2016 [55] and the validation will include a test - re-test, Cronbach's alpha and a factor analysis. Translation process will include forward translation, then

expert panel for backward translation, a pre-testing and cognitive interviewing, until we reach the final version. This procedure will be done during the pilot phase of the study that will include a sample of 100 nurses working in the emergency departments across the country. Those 100 nurses will be included only for the pilot study and not for the main study. As nurses from the emergency department are not included in the main study, pilot study was selected to take place among this group of nurses. Furthermore, nurses working in emergency departments do not provide care to PwD that last more than one day, although PwD visit the particular department on frequent occasions. So, we concluded that it is interesting to investigate emergency department nurses' level of knowledge and attitudes, considering the frequent, but short term visit of PwD to the department. For the first attempt of this intervention we decided to include nurses from the general department since they have closer contact and care for longer periods for patients with dementia. We are planning to include emergency department nurses at a later stage.

Stage 2 observation study to detect any missed nursing care towards PwD

Data from the observational study will be collected through field notes, in order to investigate care provided to PwD. Based on the hypothesis that if nurses' knowledge is low and their attitudes are negative, there is the possibility that care is not up to the expected quality standards. These data are expected to give more information as to the care of PwD and especially care deficits, care omissions and missed care, aiming to strengthen the training program and focus on specific issues that will facilitate the care delivered to this group of patients.

We have conducted a scoping review considering the methodology of observational study, so as to proceed with our design [56-62]. The observer will be the main researcher, who is a nurse. One week training and one week pilot study will precede the main study. The pilot study will include the determination and familiarization with the environment, the data collection process and co-ordination with the observation timetable [62]. This duration of time is expected to eliminate any factors that may influence nurses' behavior, due to observer presence. Reliability of the data, on stage 2, can be doubted, as nurse will not perform normal procedures with an observer in the room, but we expect that after 2

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3 weeks of observer stay they will feel comfortable and continue their everyday routine.
4 This is the reason that data from the first two weeks are not going to be analyzed.
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7 The potential for nursing omissions towards PwD is a fairly sensitive issue that, if is
8 explored through questionnaires, nurses may hide some information about what is
9 actually done because of the fear of questioning their professionalism, so the observation
10 method is expected to reflect a more objective picture of reality. Moreover, is the only
11 method that can collect data from real settings and the validity and objectivity cannot be
12 doubted, since the data are collected by an external observer. Field notes will not include
13 any characteristic of patient or nurses.
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20 *a) Sample*
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22 The sample will include PwD, who are hospitalized for any reason. The sample strategy
23 in observational studies is purposeful sampling, since the particular research topic is
24 investigated in a pre-determined population. A patient will be observed for one shift daily
25 (morning or evening). The night shift has been excluded, due to its uneven duration
26 which is 12 hours compared to the 6-hours shift (morning-evening). The sample size will
27 be determined by the data saturation criterion.
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34 In qualitative methods, the sample is smaller and when the data renewal no longer exists,
35 the collection process is considered adequate [63, 64]. Inclusion criteria will be the
36 diagnosis of dementia [65, 66] and the hospitalization of the person with dementia,
37 regardless of the reasons. The researcher will be informed at the beginning of the shift by
38 the departmental officer if PwD are hospitalized in the department. The researcher will
39 ensure and manage confidentially the data and diagnosis and cannot use them for the
40 purposes of any other research. In the case of more than one patient per ward, random
41 sampling will be performed, and data will be collected for one patient at a time and then
42 the patient will not be included again in the sample.
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50 *b) Duration of observation*
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52 The duration of the observational study will last 1 day per patient. If there is availability
53 of patients the data collection process will last 10-12 days. In other case the process will
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last until we reach 10 patients, with the maximum duration one month [56, 59, 61,62,67,68].

(c) Wards

The departments that are going to be observed are Medical, Surgical and Orthopedic in one of the five selected hospitals. The specific sections of the hospital were selected on the basis of the Alzheimer's Society report [21], 2009, which showed that 14% of patients with dementia were admitted to hospital after falls, 12% for hip replacement, 9% for urinary tract infection, 7% for respiratory infection and 7% due to stroke. In addition, another study [69] added to the above mentioned reasons dehydration, as well.

The observer will stay in the patients' room, not wearing a nurse uniform, preserving at least 3 meters distance from the patients' bed [63, 70] and record everything she sees in the context of care in her field notes. This distance is probably predetermined for respect patient's privacy. The observer will not participate in any intervention or error in order not to influence the result of the study and the normal process of the department, with only exception if is a life or death issue. Additionally, no communication will take place with nurses, patients, or patients' relatives during the observers' stay. Each patient will be recorded in new field notes.

d) Field notes

Data collection in the observational study will be based on field notes written by the observer, during her stay in the patient's room. The notes will be "methodological", "descriptive" and "theoretical". Descriptive field notes will include information about anything the observer watches or hears, regarding communication among nurses-patient, process and environment characteristics [71, 72]. Methodological field notes will be comprised of the technique of data collection. In particular, those notes include the process that the observer will use to write down the data, for instance the adjustment of the observer in the culture of the organization [71]. Theoretical field notes regard the conscious, controlled efforts of the researcher to come to the essence of her notes. Those notes are the personal interpretation of data by the observer [72]. More specifically, the researcher tries to understand behaviors or processes and to document some ideas,

questions, thoughts or concerns as a reflection of her data. Only the research team will be aware of the context of the field notes, so as not to influence the results of the study and to conserve the confidentiality and anonymity of the participants. Data will be coded and categorized, so content analysis will follow. As content analysis is a reflective process [73] the identification and condensation of the meaning units, the coding and the categorization into themes is going to be a repeated event, by at least two of the research team, in order to maintain the quality and the trustworthiness of the analysis [74]. Themes will emerge through the data and no software package will be used.

Stage 3 Quasi-experimental study

Once the descriptive and observation study have been completed, a quasi-experimental study, with a before and after design, which will include one group and one pre and two post tests will follow. This part of the study will include the organizing of a one day training course, which will facilitate nurses to provide a better and consistent care to PwD. The training will consist of various topics and will be conducted by dementia experts in order to describe, the pathophysiology of the disease and the appropriate care needed for these patients. The study has no costs, as the experts are willing to participate in the course free of charge. Furthermore, no economic outcomes are expected to emerge through the particular stage of the study.

The systematic review of the literature [48] considering intervention studies to nurses has detected eleven educational programs [5, 54, 75-83] with a large variety of designs. Most of them were seminars [76-83] lasting from 7 hours [76, 78], 1 day [80, 83], 3 days [77] to 15 weeks [82]. Other studies used one day workshops [75, 79], whilst another research team used a one day online seminar [52] or educational video [81]. This fact could be attributed to the deficiency of an established and validated program, so each research team created its own program for the purpose of each research.

For the purpose of the present study we have selected the “Getting to Know me” program (with the approval of the authors) [78], as it has checked validity and reliability but also it has been applied in more than one studies [78] and it has been adopted by the NHS. The creators suggest that the program can be applied to other countries, as well, as the results

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3 were beneficial for acute hospital nurses. However it is expected that after the
4 observational study, some modifications will be necessary to be introduced in order to
5 focus on minimizing missed care. In particular, based on stage 1 and 2 results the
6 program will be modified. For instance if the level of nurses' knowledge seems to be low
7 on stage 1, emphasis is going to be given on the particular topic. Regarding stage 2
8 results if missed care is detected in specific aspects of care eg. feeding, the training
9 program will focus on that. In general as far as it concerns missed care, if this is proven
10 through stage 2, a lecture focusing on this topic is going to be added in the training
11 program.
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19 a) Description of the program 20 21

22 This program is specifically designed for acute hospital nurses that provide care to PwD.
23 It includes lectures, video, a guide for communication skills, the form "Getting to know
24 me" and a 30 pages book. The main topics of lectures are introduction to dementia,
25 holistic care, communication, impact of hospital environment, person centered-care and
26 management of aggressive behavior. The program is going to be translated to Greek and
27 some modifications will take place, so as to respond to study sample's needs and to the
28 findings derived from the observation study. The modification will be an addition of an
29 experiential workshop and participants will have more interaction through role play. The
30 program will be implemented in two days and the sample will be twenty nurses per day,
31 with a total number of fifty nurses.
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40 As the program includes many interaction exercises sample size was premeditated
41 according to creators' suggestions about the number of participants, which is estimated to
42 be 20 nurses per day [78]. Participant number in those studies is also suggested by
43 literature to be maximum 40 people, divided in smaller groups [5, 52, 78,80,82]. We
44 concluded to include 25 nurses per day, so as to eliminate the risk of drop out. In
45 addition, we have conducted a power analysis and the estimated sample size was
46 calculated to include 20 participants. Response rate should be higher than 95% for the
47 reliability and validity of the study. To achieve the response rate reminder phone calls to
48 participants will take place after the duration of three months, by the PhD candidate.
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Inclusion criteria will be the same as the descriptive stage of the study. However priority will be given to nurses who work most with PwD, such as medical, orthopedic or surgical wards, since the descriptive study is going to take place among those departments. The setting of this phase is university's lecture hall and the target sample is 50 acute hospital nurses.

b) Evaluations

Three evaluations will include a) prior to the implementation of the program, b) immediately after the intervention c) the last one will take place three months after the intervention [76, 77, 83-86] in order to see if the effect of the program remains for a longer period. Data analysis will be the same as stage 1, since the tools that will be used on stage one and three are the same. The time intervals have been selected on the basis of international bibliography from interventional studies, which also studied the knowledge and attitudes of nurses in the care of dementia [8, 77, 83], or implemented other intervention programs in nurses [84-86].

Primary outcomes of this stage are 1) the evaluation of nurses' knowledge and attitudes which is expected to be advanced after the implementation of the program and 2) the reduction of nursing omissions during nursing care. Secondary outcomes is the upgrade of the quality of care provided to PwD, through the adoption of positive attitudes, 2) the reinforcement of sympathy among nurses to the particular group of patients and 3) the development of communication skills and management strategies on behalf of nurses, in order to reduce burden during nursing care of PwD.

Participants are going to be informed about the scope of the training program and their obligation to fill the three questionnaires before their registration to the training. The PhD candidate will be responsible for the information, registration and their consent to participate. The research team will be responsible for organizing, enrollment and coordinating the training course and the participation of nurses will be voluntary. If more than fifty nurses are willing to take part random sampling will be followed. A certification will be given after the completion of the last questionnaires to those who participate, in order to increase interest for joining the training course.

Data from the three stages are going to be stored in the researcher's office, where no one but the researcher is allowed entry. Data monitoring will be performed by the supervising committee and the PhD candidate will be responsible for analyzing, coding and writing the data. Furthermore, the committee will conduct range checks of the values as far as it concerns the questionnaires. Regarding the observational data two members of the committee will separately proceed to the coding process and then a discussion will follow with the PhD candidate, in order to develop thematic analysis.

The translation process has been done during September-January 2019. The pilot study has started on 3rd of February and has ended on 29th of April 2019, so data from the pilot study have already been collected. The present stage of the study is on stage 1, the descriptive part. The questionnaires were distributed, since the 10th of May, 2019, and this phase is expected to be finalized until 15th-20th of June. The first results are expected on 1st of July 2019 from the descriptive stage and until 30th of September 2019 the qualitative findings will be available. Data from the third stage are expected between 10th -17th of February 2020, since the intervention is programmed to be implemented on 19th of September 2019 and the last data that are going to be collected are three months after the intervention. The timeline of the study is illustrated on Figure 1.

DISCUSSION

Nursing care rationing can be considered as the direct indicator of quality of care deficiencies, with a clear pathway for patient outcomes and their experiences. In addition, is a key concept for early detection of problems, before major repercussions occur. Moreover, detecting nursing care rationing will result in an early recognition of a possible risk by nurses or policy makers [87]. The vulnerable group of patients with cognitive impairment is the best example of complexity in the elderly, but with the highest rates of complications occurring, during hospitalization. Omissions are not just a complete or a single unfortunate event, but a series of mild forms of neglect.

Nursing care rationing is an international phenomenon, as many studies investigated the kind of care which is missed [25, 26, 28, 33, 36-39, 46, 88], factors that influence the phenomenon [22, 27, 41, 43, 44, 89-93], the consequences on patients [19, 23, 26-28, 41,

43-45, 47, 94-96] and on nurses [28, 43, 44, 97-99]. This study aims to add to the existing model of factors associated with nursing care rationing [30] the factors of knowledge and attitudes, without marginalizing the other factors already acknowledged (environmental, organizational, administrative). None of those studies have correlated nursing care rationing with a specific group of patients and since PwD constitute a major percentage of hospitalized patients, in correlation with the rapid epidemiological growth, the topic is of high importance. All in all, this is the first study that is going to recognize if there is any correlation among low level of knowledge and quality of care and implement an educational program, so as to promote care among PwD.

Although the reasons for care rationing have been investigated, this phenomenon is even observed in cases where the workload is not much. Nurses have become so familiar with the "chaos" associated with unexpected events and breaks in their processes, so they continue to act with prioritization even when they are not imposed by other factors [22, 100]. There have been reports of doctors and nurses placing older people at a lower priority, with a lot of interventions and medications, but little care and comfort [19]. This event was described as spam, but it often happens. Prioritization seems to be implemented through traditional biomedical approaches that go beyond ethical issues [40].

The study is going to be conducted only in three wards of the hospital, although nursing care settings are differential in other wards and this is a point for consideration. During the second phase of the study the total number of nurses per ward may be affected by sick leaves or training leaves and this might influence normal nursing care procedures. The intervention will last for only one day and it is not certain that the effects will last for a long time, meaning that there will be a need to repeat educational interventions at a later stage. The generalizability of the study's results should be interpreted in the lights of these limitations.

Patient and Public Involvement

During the second stage of the study patients and their carer participation is of high importance, by consenting to being observed. If they are not willing to do so, the study design for stage two will not be achievable. Research questions were informed based on published literature regarding carers' experience during hospitalization of PwD [21]. Also, informing them that care process is going to be observed they will share with us their priorities and their opinion about hospital care, so the outcome will be on stage three, as we will update our training program based on patients' and carers' experience. During phase one and two patient and public involvement is not achievable, but stage three will be modified based on their experiences.

ETHICS AND DISSEMINATION

The protocol was approved by Cyprus National Bioethics committee (EEBK: 2018.01.02) and by the Research committee of the Ministry of Health. Access to the field of research was obtained by each hospital manager and the managers of each ward. The relatives of patients with dementia will be informed that patients will be observed and the aims of the study will be explained, so as to gain their permission.

After the observer will be informed about the rooms that hospice PwD, she will be responsible for the recruitment of the patients and their carers. She will explain to both of them the aim, the design and the volunteer nature of the study, along with contact details for all the research team. If they agree, the relative will be asked to sign on the patients' behalf for participation in the study and then the data collection will start. Since PwD are characterized by cognitive impairment, their consent is often doubted. As patients' consent is an issue of conflict in the research field [101], we decided to proceed with the general practice regarding dementia studies and request relatives' signature [102], regardless of patients' capacity. The patient will be informed despite of his/her capacity, which is not going to be assessed. Also, they will be informed that study results will be available in lectures that the researchers make in cooperation with the national Alzheimer Society. In cases that are not able to participate they can contact a member of the research team and inform them about the results of the study.

The anonymity, the trustworthiness and the process of the collected data will also be explained in the consent form both for the nurses and well as the relatives of PwD, that the data are going to be used only for the purpose of the particular study and when is finished are going to be destroyed. In order to remain the confidentiality and the anonymity of the participants none of the patients' or the nurses' identification will be included. Patients are going to be coded and no one except from the main researcher will be able to know to whom the data are referred. The research team will be the only one who will have access to the data. If any important modification of the protocol will take place all the relevant parties will be informed (Ethics Committee, Health Ministry). This study is in conjunction with the SPIRIT statement [103].

Dissemination strategy includes presentations in international and national scientific conferences. More emphasis will be given in nursing conferences, as the audience will be more benefited in clinical practice. All the results are going to be submitted in peer-reviewed journals for publication. Moreover, the results of the intervention stage are going to be presented in policy makers in order for the program to be implemented in a broader population of nurses. The results of the study are going to inform future study, as well, targeting carers of PwD and evaluate if the usefulness is as important as to nurses.

Author statement

Authors' contributions: Melina Evripidou has written the manuscript. Evridiki Papastavrou as the main supervisor of the project, contributed and supervised the writing process, reviewed the manuscript and consulted the first author. Anastasios Merkouris and Andreas Charalambous have reviewed and contributed in writing the manuscript.

Funding: The research is supported by Leventis foundation grant number EPI009/181120/820750. Publication fees were granted by the Cyprus University of Technology Open Access Author Fund.

Competing interests: The authors declare that they have no competing interests.

Acknowledgements: The authors gratefully acknowledge nurses and departmental officers for their cooperation and the permission to conduct the observation study to their wards.

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References

1. Alzheimer’s Association. Alzheimer’s disease facts and figures. 2016. Available at: http://www.alz.org/documents_custom/2016-Facts-and-Figures-Fact-Sheet.pdf. Accessed 19 March 2019.
2. WHO. Dementia: a public health priority. 2012. Available at: http://www.who.int/mental_health/publications/dementia_report_2012/en/. Accessed 14 February 2019.
3. Knapp M. Economic outcomes and levers: impacts for individuals and society. *IntPsychogeriatr*. 2007;19(3):483-95.
4. Robinson A, Eccleston C, Annear M, Elliott K.E, Andrews S, Stirling C, Ashby M, Donohue C, Banks S, Toye C. &McInerney F. Who knows, who cares? Dementia knowledge among nurses, care workers, and family members of people living with dementia. *JournalofPalliativeCare*.2014; 30(3):158–165.
5. Bryans M, Keady J, Turner S, Wilcock J, Downs M &Iliffe S. An exploratory survey into primary care nurses and dementia care. *British Journal of Nursing*.2003;12(17):1029–1037.

6. Kada S, Nygaard H.A, Mukesh B.N &Geitung J.T. Staff attitudes towards institutionalized dementia residents. *Journal of Clinical Nursing*.2009;18(16): 2383–2392.

7. Josefsson K, Sonde L &Wahlin T.-B.R. Competence development of registered nurses in municipal elderly care in Sweden: a questionnaire survey. *International Journal of Nursing Studies*.2008;45(3):428–441.

8. Galvin J.E, Kuntemeier B, Al-Hammadi N, Germino J, Murphy-White M & McGillick J. “Dementia-friendly hospitals. *Alzheimer Disease & Associated Disorders*.2010;24(4):372–379.

9. Marx K.A, Stanley I.H, Van Haitisma K, Moody J, Alonzi D, Hansen B.R &Gitlin L.N. Knowing versus doing: Education and training needs of staff in a chronic care hospital unit for individuals with Dementia. *Journal of Gerontological Nursing*.2014;40(12):26–34.

10. Barrett J.J., Haley W.E., Harrell L.E. & Powers R.E. Knowledge about Alzheimer disease among primary care physicians, psychologists, nurses, and social workers. *Alzheimer Disease & Associated Disorders*.1997;11(2):99–106.

11. International Federation of Red Cross and Red Crescent Societies (IFRC). What is vulnerability?. 2014. <http://www.ifrc.org/en/what-we-do/disaster-management/about-disasters/what-is-a-disaster/what-is-vulnerability/>. Accessed 21th January 2019.

12. Centers for Disease Control and Prevention (CDC). Elder Abuse. 2017. <https://www.cdc.gov/violenceprevention/elderabuse/index.html>. Accessed 3rd January 2019.

13. Centers for Disease Control and Prevention (CDC). Elder Abuse. 2017. <https://www.cdc.gov/violenceprevention/elderabuse/index.html>. Accessed 3rd January 2019.

14. WHO. Management of substance abuse. Process of translation and adaption of instruments.2016. http://www.who.int/substance_abuse/research_tools/translation/en/. Accessed 13th March 2019.

15. Dixon J, Manthorpe J, Biggs S, Mowlam A, Tennant R., Tinker A&McCreadie C.
Defining elder mistreatment: Reflections on the United Kingdom study of abuse
and neglect of older people. *Ageing & Society*.2010;30(3)403–420.
16. Gilhooly M.L.M, Cairns D, Davies M, Harries P, Gilhooly K.J, Notley E.
Framing the detection of financial elder abuse as bystander intervention: Decision
cues, pathways to detection and barriers to action. *Journal of Adult
Protection*.2013;15(2):54–68.
17. Manthorpe J. Elder abuse. In: Dening. Oxford textbook of old age psychiatry (2nd
ed.), Oxford: Oxford University Press. 2013. p.779-83.
18. Manthorpe J. The abuse, neglect and mistreatment of older people with dementia
in care home and hospitals in England: the potential for secondary data analysis:
innovative practice. *Dementia*.2015;14(2):273-9.
19. Skirbekk H. & Nortvedt P. Making a difference: A qualitative study on care and
priority setting in health care. *Health Care Analysis*.2011;19(1):77–88.
20. Boyle M, Williams B, Tedd B, Molloy A.et al. Attitudes of undergraduate health
science students towards patients with intellectual disability, substance abuse, and
acute mental illness: a cross-sectional study. *BMC Medical Education*. 2010.
<https://bmcmmededuc.biomedcentral.com/articles/10.1186/1472-6920-10-71>.
Assessed 22th February 2019.
21. Alzheimer Society. Counting the cost. 2009.
https://www.alzheimers.org.uk/download/downloads/id/787/counting_the_cost.pdf
f. Accessed 9th February 2019.
22. Kalisch B.J, Landstrom G.L. & Hinshaw A.S. Missed nursing care: A concept
analysis. *Journal of Advanced Nursing*.2009;65(7):1509–1517.
23. Kalisch B,Tschannen D, Lee H, FrieseC. Hospital variation in missed nursing
care. *Am J Med Qual*.2012;26(4):291–299.
24. Scott P. A, Harvey C, Felzmann H, Suhonen R, Habermann M, Halvorsen K,
Papastavrou E. Resource allocation and rationing in nursing care: A discussion
paper. *Nursing Ethics*.2018; <https://doi.org/10.1177/0969733018759831>
25. Papastavrou E. The ethics of care rationing within the current socioeconomic
constraints. *Health Science Journal*.2012;6(3):362–364.

26. Ball J, Griffiths P, Rafferty A.M., Lindqvist R, Murrels T. QUANTITATIVE A cross-sectional study of ‘care left undone’ on nursing shifts in hospitals. *J of AdvNurs*. 2016;72(9):2086-97.

27. Schubert M, Carke S, Glass T, Schaffert-Witvliet B, De Geest S. Identifying thresholdsfor relationship between impacts of rationing of nursing care and nurse and patient reported Outcomes in Swiss hospitals : A correlational study.*Int J nurs Stud*.2010; 46(7):884–893.

28. Papastavrou E, Andreou P, Efstathiou G. Rationing of nursing care and nurses-patient outcomes: a systematic review of quantitative studies. *Int J Health Manage*.2014;2(1):3-25.

29. Verall C, Abery E, Harvey C, Henderson J, Willis E, Hamilton P, Toffoli L, Blackmann I. Nurses and midwives perceptions of missed nursing care--A South Australian study.*Collegian*.2015;22(4).413-20.

30. Blackman I. Factors influencing why nursing care is missed. *Journal of Clinical Nursing*.2015;24(1–2):47–56.

31. Nortvedt P, Hem M.H. & Skirbekk H. The ethics of care: Role obligations and moderate partiality in health care. *Nursing ethics*.2011;18(2):192–200.

32. Jones T, Hamilton P, Murry N. Unfnished nursing care, missed care and implicitly rationad care: state of the science review. *Int J of Nusing Studies*.2015;52(6): 1121-37.

33. Kalisch BJ, Xie B, Dabney BW. Patient-reported missed nursing care correlated with adverse events. *Am J Med Qual*.2014;29:415–22.

34. Kalisch BJ, Tschannen D, Lee KH. Missed nursing care, staffing, and patient falls. *J NursCare Qual*.2012;27:6–12

35. Lucero R. Nursing Informatics Implications from a Study of Unmet Nursing Care Needs. *Connecting Health and Humans*.2009;5043:817–821.

36. Aiken LH, Sloane D, Griffiths P For the RN4CAST Consortium, et al. Nursing skill mix in European hospitals: cross-sectional study of the association with mortality, patient ratings, and quality of care. *BMJ Qual Saf*.2017;26:559-568.

37. Morin D, Leblanc N. Less money, less care: how nurses in long-term care allocate hours of needed care in a context of chronic shortage. *Int J Nurs Pract*.2005;

- 11(5):214–220.
38. Kalisch B.J, Xie B. Errors of omission: missed nursing care. *Western J. Nurs. Res.* 2014;36(7): 875–890.
39. Knopp-Sihota JA, Niehaus L, Squires JE, Norton PG, Estabrooks CA. Factors associated with rushed and missed resident care in western Canada nursing homes: a cross-sectional survey of health care aides. *J Clin Nurs.* 2015;24:1815–25.
40. Pedersen R, Nortvedt P, Nordhaug M, Slettebo A, Grothe KH et al. In quest of justice? Clinical prioritisation in healthcare for the aged. *Journal of medical ethics.* 2008;34(4):230–5.
41. Schubert M, Glass TR, Clarke SP, Schaffert-Witvliet B, De Geest S. Validation of the baseline extent of rationing of nursing care instrument. *Nurs Res.* 2007;55(6):416–424.
42. Sochalski J. Is more better?: the relationship between nurse staffing and the quality of nursing care in hospitals. *Med Care.* 2004;42(2):II-67–II-73.
43. Ausserhofer D, Schubert M, Desmedt M, Blegen M.A., De Geest S., Schwendimann R. The association of patient safety climate and nurse-related organizational factors with selected patient outcomes: a cross-sectional survey. *Int. J. Nurs. Stud.* 2013;50(2):240–252.
44. Ausserhofer D, Zander B, Busse R, Schubert M, De Geest S, Rafferty A.M, et al. Prevalence, patterns and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. *Br. Med. J. Qual. Safety.* 2014;23(2):126–135.
45. Lucero R.J, Lake E.T, Aiken L.H. Nursing care quality and adverse events in US hospitals. *J. Clin. Nurs.* 2010;19(15–16):2185–2195.
46. Hayward R.A, Asch S.M, Hogan M.M, Hofer T.P, Kerr E.A. Sins of omission: getting too little medical care may be the greatest threat to patient safety. *J. Gen. Intern. Med.* 2005;20:686–691.
47. Brown P, Fraser K, Wong CA, Muise M, Cummings G. Factors influencing intentions to stay and retention of nurse managers: a systematic review. *J Nurs Manag.* 2012; DOI: 10.1111/j.1365-2834.2012.01352.x
48. Evripidou M, Charalambous A, Middleton N, Papastavrou E. Nurses' knowledge

and attitudes about dementia care: systematic literature review.
PerspectivPsychiatr Care 2018.Doi: 10.1111/ppc.12291.

49. Toye C, Lester L, Popescu A, McInerney F, Andrews S, Robinson AL. Dementia Knowledge Assessment Tool Version Two: development of a tool to inform preparation for care planning and delivery in families and care staff.*Dementia* (London).2014;13(2):248-56.

50. O'Connor M, McFadden S. Development and Psychometric Validation of Dementia Attitude Scale. *Int J of Alzheimer Disease*.2010.doi: 10.4061/2010/454218.

51. Robinson A, Eccleston C, Annear M, Elliott K.E, Andrews S, Stirling C, Ashby M, Donohue C, Banks S, Toye C. &McInerney F. Who knows, who cares? Dementia knowledge among nurses, care workers, and family members of people living with dementia. *Journal of Palliative Care*.2014;30(3):158–165.

52. Kimzey M, Matel-Smith B, Alfred D. The impact of educational experiences on nursing students' knowledge and attitudes toward people with Alzheimer's disease: A mixed method study. *Nurse Education Today*.2016;46:57-63.

53. Scerri A, Scerri C. Nursing students' knowledge and attitudes towards dementia- a questionnaire survey. *Nurse Education Today*.2012;33(9):962-8.

54. Breckler S.J. "Empirical validation of affect, behavior, and cognition as distinct components of attitude". *Journal of Personality and Social Psychology*.1984; 47(6):1191–1205.

55. WHO. Management of substance abuse. Process of translation and adaption of instruments.2016.
http://www.who.int/substance_abuse/research_tools/translation/en/.Accessed 13th September 2018.

56. Välimäki T, Vehviläinen-Julkunen K, Pietilä AM. Diaries as research data in a study on family caregivers of people with Alzheimer's disease: methodological issues. *J AdvNurs*.2007;59(1):68-76.

57. Ballermann MA, Shaw NT, Mayes DC, Gibney RT, Westbrook JI. Validation of the Work Observation Method By Activity Timing (WOMBAT) method of

- conducting time-motion observations in critical care settings: an observational study. *BMC Med Inform Decis Mak*.2011;17:11:32.
58. Jackson D, Wilkes L, Luck L. Cues that predict violence in the hospital setting: findings from an observational study. *Collegian*.2014;21(1):65-70.
59. D'Antonio S, Bagnasco A, Bonetti L, Sasso L. Observation study on interruptions during nurses work in two surgical wards of a hospital in Liguria. *Prof Inferm*.2014;67(4):211-8.
60. Clisset P, Porock D, Harwood RH, Gladman JR. The response of healthcare professionals to the admission of people with cognitive impairment to acute hospital setting: an observation and interview study. *J Clin Nurs*.2014;23(13-14):1820-9.
61. Hoviattalab K, HashemizadehH,Cruz G, Halfens Ruud J G, Dassen T. Nursing practice in the prevention of pressure ulcers : An observational study of German Hospitals Nursing practice in the prevention of pressure ulcers : an observational study of German Hospitals. *J Clin Nurs*.2015;11-12:1513-24.
62. Tan Y, Wai T, Sim C,I Ng. Optimising peripheral venous catheter usage in the general inpatient ward : a prospective observational study. *JClin Nurs*.2016;26:133-39.
63. Cohen L, Manion L, & Morrison K. Research methods in education. London, Routledge.2007.
64. Marshall M. Sampling for qualitative research. *Family Practice*.1996;13(6):5225.
65. Streit S, Limacher A, Zeller A, Burrge M. D. Detecting dementia in patients with normal neuropsychological screening by Short Smell Test and Palmo-Mental Reflex Test: an observational study. *BMC Geriatrics*.2015;15:90.
66. Travers C, Byrne G.J, Pachana NA, Klein K, Gray LC. Prospective observational study of dementia in older patients admitted to acute hospitals. *Australas J Ageing*.2014;33(1):55-8.
67. Hager K, Calabrese P, Frolich L, Gobel C, Berer FM. An observational clinical study of the efficacy and tolerability of donepezil in the treatment of Alzheimer's disease. *Dement GeriatrCogn Disord*.2003;15(4):189-98.
68. Goudra B, Singh P.M,Galvin E. Comparison of Compliance of Glove Use Among

Anesthesia Providers: A Prospective Blinded Observational Study. *AANA Journal*.2014; 82(5):363-67.

69. Natalwala A, Potluri R, Uppal H, Heun R. Reasons for hospital admissions in dementia patients in Birmingham, UK, during 2002-2007.*Dementia GeriatrCogn Disord*.2008;26(6):499-505.

70. Creswell J, Vicki L, Plano C. Designing and conducting mixed method research. Los Angeles: SAGE Publications. 2011.

71. Bernard H.R. Research methods in anthropology: Qualitative and quantitative approaches. Lanham, MD: AltaMira Press.2011.

72. Lonner W.G, Berry J.W. Field notes in cross-cultural research. Newbury Park.CA: Sage Publications. 1986.

73. Erlingsson G, Brysiewicz P. A hands-on guide to doing content analysis. *African Journal of Emergency Medicine*.2017;7(3):93-99.

74. Bengtsson M. How to plan and perform a qualitative study using content analysis. *Nursing plan open*.2016;2:8-14.

75. Kang Y, Moyle W, Venturato L. Korean nurses' attitudes towards older people with dementia in acute care settings. *International Journal of Older People Nursing*.2011;6(2):143-152.

76. Galvin J.E, Kuntemeier B, Al-Hammadi N, Germino J, Murphy-White M. &McGillick J. “Dementia-friendly hospitals. *Alzheimer Disease & Associated Disorders*.2010;24(4):372–379.

77. Surr C.A, Smith S.J, Crossland J. & Robins J. Impact of a person-centred dementia care training programme on hospital staff attitudes, role efficacy and perceptions of caring for people with dementia: a repeated measures study. *International Journal of Nursing Studies*.2015;53:144–151.

78. Elvish R, Burrow S, Cawley R, Harney K, Graham P, Pilling M, Gregory J, Roach P, Fossey J. & Keady J. ‘Getting to know me’: the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & Mental Health*.2014;18(4):481–488.

79. Manthorpe J, Iliffe S. & Eden A. Early recognition of dementia by nurses.
Journal of Advanced Nursing.2003;44(2):183–191.
80. Davison T.E, McCabe M.P, Visser S, Hudgson C, Buchanan G. & George K.
Controlled trial of dementia training with a peer support group for aged care staff.
International Journal of Geriatric Psychiatry.2007;22(9):868–873.
81. EinangAlnes R, Kirkevold M. &Skovdahl K. Insights gained through MarteMeo
counselling: experiences of nurses in dementia specific care units. *International
Journal of Older People Nursing*.2011;6(2):123–132.
82. McCaffrey R, Tappen R.M, Lichtstein D.M. &Friedland M. Interprofessional
education in community-based Alzheimer’s disease diagnosis and treatment.
Journal of Interprofessional Care.2013;27(6):1356–1820.
83. Palmer J.L, Lach H.W, McGillick J, Murphy-White M, Carroll M.B. &
Armstrong J.L. The dementia friendly hospital initiative education program for
acute care nurses and staff. *The Journal of Continuing Education in
Nursing*.2014;45(9):416–424.
84. Gustafsson M, Bohman DM, Borglin G. Challenges of conducting experimental
studies within a clinical nursing context. *ApplNurs Res*.2014;27(2):133-6.
85. Borglin G, Gustafsson M, Krona H. A theory-based educational intervention
targeting nurses' attitudes and knowledge concerning cancer-related pain
management: a study protocol of a quasi-experimental design. *BMC Health Serv
Res*.2011;23(11):233.
86. Mahedran R, Tan J,Griva K, Lim H, Ng H.Y, Chua J,Lim, SE and Kua EH. A
pilot, quasi-experimental, mixed methods investigation into the efficacy of a
group psychotherapy intervention for caregivers of outpatients with cancer: the
COPE study protocol. *BMJ Open*.2015; 5(11):e008527.
87. Bail K, Berry H, Grealish L, Draper B, Karmel R, Gibson D. &Peut A. Potentially
preventable complications of urinary tract infections, pressure areas, pneumonia,
and delirium in hospitalised dementia patients: Retrospective cohort study.*BMJ
Open*.2013;3:6.

88. Papastavrou E, Charalambous A, Vryonides S, Eleftheriou C, Merkouris A. To what extent are patients' needs met on oncology units? The phenomenon of carer rationing. *Eur J Oncol Nurs*.2016;21:48-56.

89. Chassin M.R, Galvin R.W. The National Roundtable on Health Care Quality. The urgent need to improve health care quality: Institute of Medicine National Roundtable on Health Care Quality. *J. Am. Med. Assoc.*1998;280(11):1000–1005

90. El-Jardali F, Lagace M. Making hospital care safer and better: the structure–process connection leading to adverse events. *Healthc. Q.*2005;8(2):40–48

91. Halvorsen K, Slettebø A, Nortvedt P, Pedersen R, Kirkevold M, Nordhaug M, Brinchmann BS. Priority dilemmas in dialysis – The impact of old age Priority dilemmas in dialysis : the impact of old age. *J Med ethics*.2008;34(8):585-9.

92. Tschannen D, Kalisch BJ, Lee KH. Missed nursing care: the impact on intention to leave and turnover. *Can J Nurs Res*.2010;42(4):22–39

93. Castner J, Wu Y.W.B, Dean-Baar S. Multi-level model of missed nursing care in the context of hospital merger. *Western J. Nurs.Res.*2014.
<http://dx.doi.org/10.1177/0193945914535670> Accessed 11th January 2019.

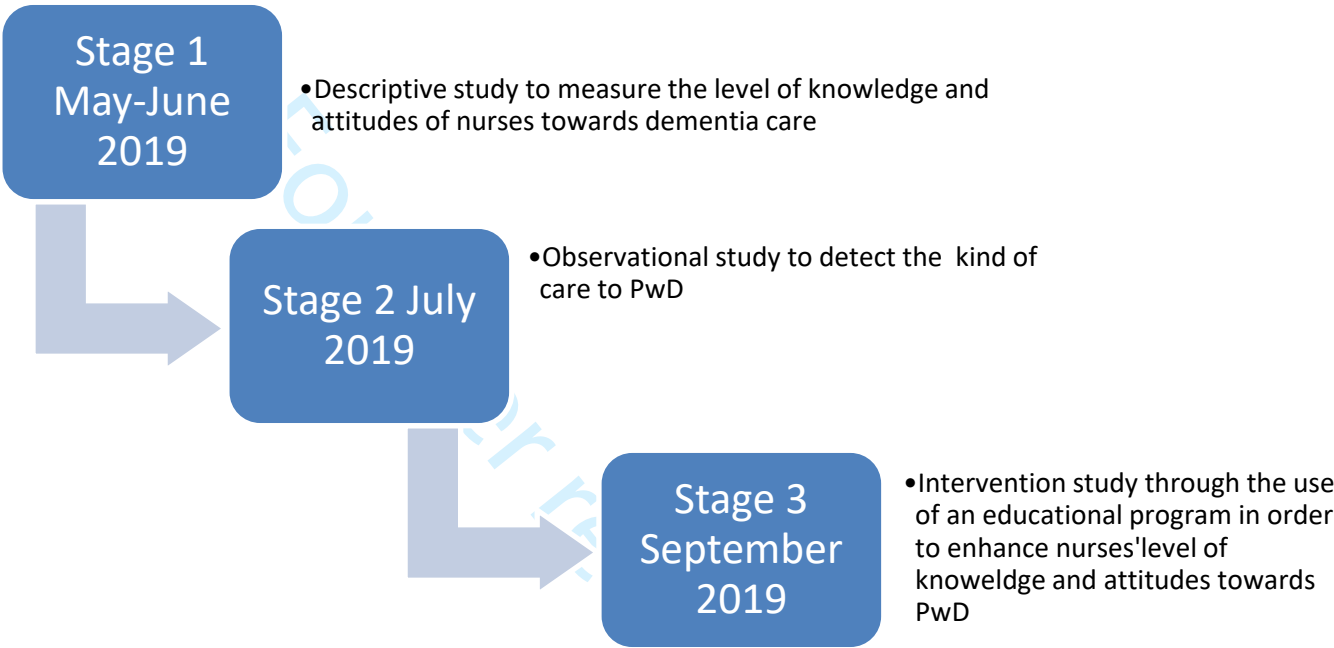
94. Williams J. Care quality Commission Dignity and nutrition inspection program: National overview.2011.https://www.cqc.org.uk/sites/default/files/documents/20111007_dignity_and_nutrition_inspection_report_final_update.pdf Accessed 1st October 2018.

95. McWhirter JP, Pennington CR. Incidence and recognition of malnutrition in hospital. *BMJ*.1994;308(6934):945-8.

96. Rochefort CM, Clarke S. Nurses' work environments, care rationing, job outcomes, and quality of care on neonatal units. *J Adv Nurs*.2010;66(10):2213–2224.

97. Dhaini SR, Zúñiga F, Ausserhofer D, Simon M, Kunz R, De Geest S, Schwendimann R. Care workers health in Swiss nursing homes and its association with psychosocial work environment: A cross-sectional study. *Int J Nurs Stud*.2016;53:105-15.

- 1
2
3 98. Vryonides S, Papastavrou E. & Charalambous A. The ethical dimension of
4 nursing care rationing : A thematic synthesis of qualitative studies. *Nursing*
5 *Ethics*.2015;22(311):881–900.
6
7
8 99. Vryonides S, Papastavrou E, Charalambous A, Andreou P, Eleftheriou
9 C, Merkouris A. Ethical climate and missed nursing care in cancer care units.
10 *Nurs Ethics*.2016;27.pii:0969733016664979.
11
12 100. Kalisch BJ. Missed nursing care: a qualitative study. *J Nurs Care*
13 *Qual*.2006;21(4):306–313.
14
15 101. Howe E. Informed Consent, participation in research and the Alzheimer patient.
16 *Innov Clin Neurosci*. 2012;9:47-51.
17
18
19
20
21 102. Hedge S, Ellajisyula R. Capacity issues and decision-making in dementia. *Ann*
22 *Indian Acad Neurol*. 2016;19:34-39.
23
24 103. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić
25 K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W,
26 Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D.
27 SPIRIT 2013 Statement: Defining standard protocol items for clinical
28 trials. *AnnIntern Med*.2013;158:200-207.
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Check
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	N/A
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	35
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 35
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	8

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	N/A
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	17-18
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	18
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	17
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	19
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14, 17

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	18
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Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	18
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	18
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	18
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11,15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18-19

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18-19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	21
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14,16,20,21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	35
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	35
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	11, 20
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.